

The
Aesthetic
Society

PLEASE MUTE YOUR AUDIO AND VIDEO

zoom

A black Zoom control bar containing three buttons: 'Unmute' (with a microphone icon and a red slash), 'Start Video' (with a video camera icon and a red slash), and 'Chat' (with a speech bubble icon). Each button has a small upward-pointing arrow above it.

Unmute Start Video Chat

Disclaimer:

Providing ideas and not legal advice

All information presented as of
October 21, 2020



Patient Decision Aid Series:

Cutting Edge Patient Education

&

*Informed Consent for Primary Breast
Augmentation*



Made Possible by an Educational Grant from Allergan Aesthetics

Panelists



CHELSEA HAGOPIAN, DNP,
APRN, AGACNP-BC



LAURIE A. CASAS MD, FACS



MELINDA HAWS, MD

why is shared decision-making important in plastic surgery?

“A [shared decision-making] process of communication, if properly performed and documented in the patient’s record, would constitute **perfected informed consent.**”

Birkeland S, Moulton B. Shared Decision-Making and Liability in Aesthetic Surgery. *Aesthet Surg J.* 2016;36(8):NP254-NP255.

Download the PDA at:
www.surgery.org/pda

Making quality decisions about primary breast augmentation surgery

A decision aid to support informed choices that reflect best evidence and what matters most to you

What is the purpose of this decision aid?

This decision aid is designed to prepare you for decision-making and to facilitate shared decision-making with your plastic surgeon, by helping to:

- introduce the decisions necessary to consider before primary breast augmentation surgery,
- educate you on the essential information you need to know to make each decision, and
- identify your goals, values, and preferences relevant to each decision and clearly communicate them to your plastic surgery care team.

Who should use this decision aid?

This decision aid is for you if:

- You are a woman age 18 or older, and
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 - gender affirming male-to-female surgery.
- Breast implant surgery for reconstructive, revision, or gender affirming reasons have different or additional information essential for decision-making but not covered in this decision aid, including options, risks, benefits, expectations or limitations.

What content is and is not covered in this decision aid?

- This decision aid includes only the information considered essential for all patients to understand before surgery when considering primary breast augmentation surgery.
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How should I use this decision aid?

Use this decision aid before and throughout the consultation and informed consent process with your board-certified plastic surgeon. It is structured to help you answer the following questions:

How should I
prepare for
decision-making?

Is plastic surgery
right for me?

Should I have
breast augmentation
surgery?

What questions
should I ask my
plastic surgeon?

What are my
next steps?

Agenda

01 overview of patient decision aids (PDAs) & shared decision-making

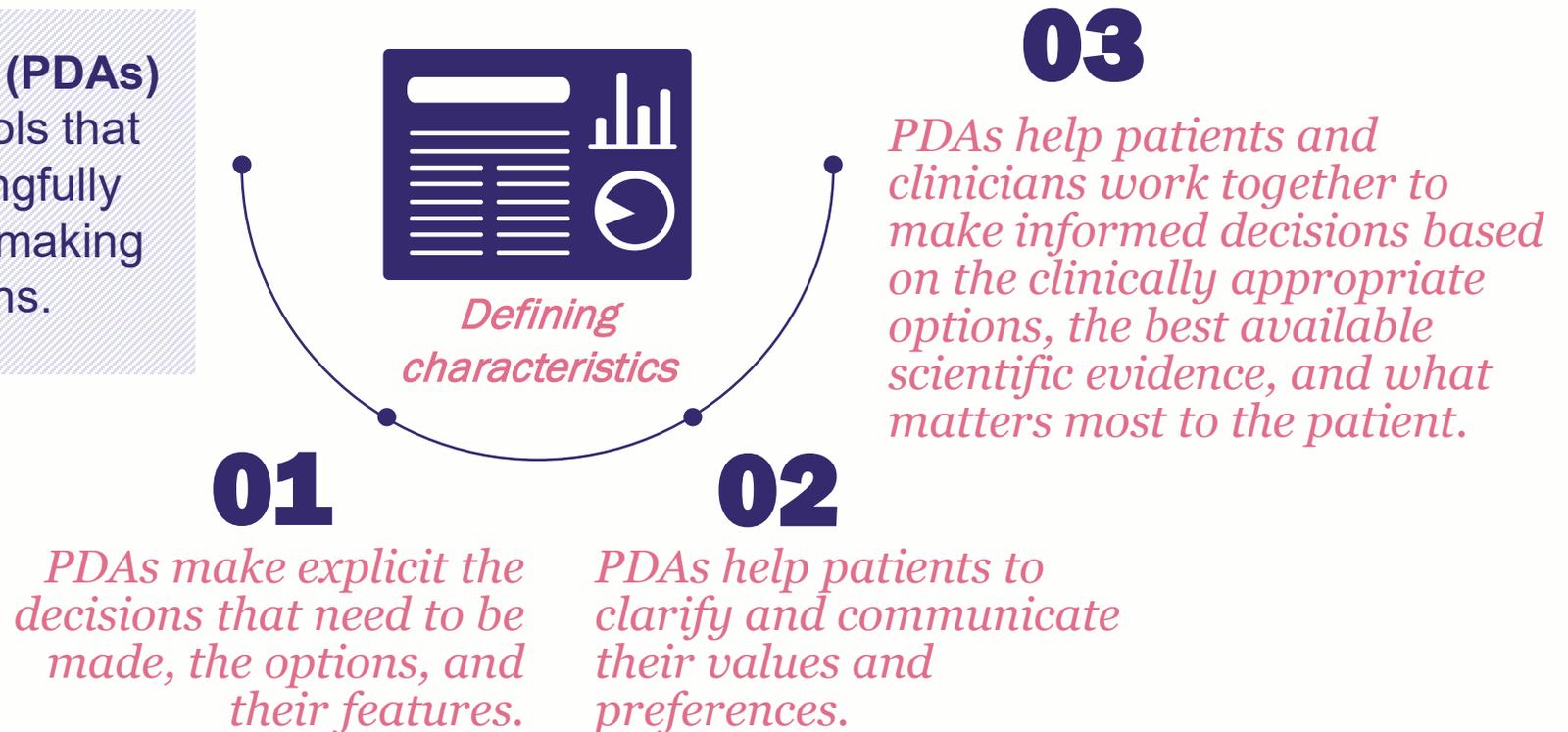
02 highlight key features of the PDA & relevant research

patient decision aids & shared decision-making

overview
& published standards

what is a patient decision aid?

Patient decision aids (PDAs) are evidence-based tools that help patients to meaningfully participate in decision-making about healthcare options.



traditional informed consent documents v. patient decision aids

The informed consent process should work *for* you, not *against* you. Traditional informed consent documents are a source of waste in healthcare and are focused on clinician disclosure, not patient understanding.¹⁻³ Informed consent is a *process*, not a form.⁴ Patient decision aids PDAs can help to make best practice, common practice

<i>Traditional informed consent document (ICD)</i>	<i>Patient decision aid (PDA)</i>
Passive	Active
Signature on a form to <u>conclude</u> informed consent	Interactive tool to <u>prepare</u> patients for informed consent conversations & <u>facilitate</u> shared decision-making
One-way communication (clinician disclosure)	Two-way communication (education and mutual understanding)
Variability (depth, breadth & quality of content)	Reliability (evidence-based; leverages deference to expertise)
Content-oriented (type of information)	Context-oriented (essential information applied to the relevant decision)
Ineffective “ritualistic” formality ⁵	Evidence-based standards for ensuring quality

limitations of checklists & warnings

Checklist & *box* warnings do not:

- X capture patient baseline understanding of concern(s) & available treatment options
- X help to elicit patient goals, values & informed preferences
- X assess comprehension
- X reconcile misunderstanding of information
- X confirm a mutually [patient/clinician] agreed upon treatment plan
- X ensure compliance with national health literacy or numeracy guidelines, nor
- X adhere to risk communication principles



Checklists

Consider as a call for process reliability and decreased variation in information disclosure



Box warnings

Recognizes a need for easily identifiable essential information

shared decision-making & PDAs...

improve:

- patient knowledge about risks & benefits^{1,2}
- decision concordance with patient values²

reduce:

- decisional conflict^{1,2}



standards for developing & evaluating patient decision aids

Minimum standards for **screening** and **certification** are published by the **National Quality Forum (NQF)**.

National Quality Forum (NQF). National Quality Partners Playbook™: Shared Decision Making in Healthcare. 2018. pp 32-33.

standards for developing & evaluating patient decision aids

screening criteria for PDA eligibility	certification criteria
1. Describes the health condition or problem for which a decision is required.	1. Provides a balanced presentation of options.
2. Identifies the target user.	2. Contains content based on a rigorous and documented evidence synthesis method.
3. Explicitly states the decision under consideration.	3. Provides information about the evidence sources used.
4. Describes the options available for the decision, including nontreatment when appropriate.	4. Provides key outcome probabilities, adopting risk communication principles.
5. Describes the positive features of each option.	5. Provides a publication date.
6. Describes the negative features of each option.	6. Provides information about the update policy and next expected update.
7. Clarifies patient values for outcomes of options by: <ul style="list-style-type: none"> b. asking patients to consider or rate which positive and negative features matter most to them; and/or c. describing the features of options to help patients imagine the physical and/or social and/or psychological effects. 	7. Provides information about the funding sources used for development.
	8. Provides information about competing interests and/or policy.
	9. Provides information about the patient decision aid development process, including information about participation from target users and health professionals.
	10. Provides information about user testing with target patients and health professionals.
	11. Reports readability levels.
	12. Follows plain language guidelines, to ensure understanding of people with low literacy and/or low health literacy skills.

standards for developing & evaluating patient decision aids

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standards for developing & evaluating patient decision aids

Detailed criteria for evaluating the **quality** of PDAs is published by the International Patient Decision Aid Standards (IPDAS) Collaboration.

International Patient Decision Aid Standards (IPDAS) Collaboration. IPDAS 2005: Criteria for Judging the Quality of Patient Decision Aids. http://ipdas.ohri.ca/IPDAS_checklist.pdf

A to Z Inventory of Decision Aids

Patient Decision Aids

For specific conditions

For any decision

Developed in Ottawa

Other KT Tools

Decision Coaching

Conceptual Frameworks

Decision Aid Summary

Title	Making quality decisions about primary breast augmentation surgery.
Audience	Adult (age 18 or older) females actively considering primary breast augmentation (enlargement) surgery with saline or silicone implants for cosmetic reasons.
Options included	Is plastic surgery right for me? Should I have breast augmentation surgery?

Based on [IPDAS criteria \(International Patient Decision Aid Standards\)](#) this decision aid (and/or supporting materials) meets:*

7 out of 7 criteria to be defined as a patient decision aid

8 out of 8 criteria to lower the risk of making a biased decision

Not applicable: other criteria for decision aids about screening or testing

*PDA summary for *Making quality decisions about primary breast augmentation surgery*

Mission & History

People

Funding

Website Statistics

News & Events

Search this site

Google Search

Type of decision aid	Treatment
Language	English

Based on [IPDAS criteria \(International Patient Decision Aid Standards\)](#) this decision aid (and/or supporting materials) meets:

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A to Z Inventory of Decision Aids

- [Online database](#) of patient decision aids
- Made publicly-available by the Ottawa Hospital Research Institute
- [PDA summary](#) for *Making quality decisions about primary breast augmentation surgery*

Checklist

Criteria to be defined as a patient decision aid	Answer
• The decision aid describes the condition (health or other) related to the decision.	Yes
• The decision aid describes the decision that needs to be considered (the index decision).	Yes
• The decision aid identifies the target audience.	Yes
• The decision aid lists the options (health care or other).	Yes
• The decision aid has information about the positive features of the options (e.g. benefits, advantages).	Yes
• The decision aid has information about negative features of the options (e.g. harms, side effects, disadvantages).	Yes
• The decision aid helps patients clarify their values for outcomes of options by: a) asking people to think about which positive and negative features of the options matter most to them AND/OR b) describing each option to help patients imagine the physical, social, and /or psychological effect.	Yes

Criteria to lower the risk of making a biased decision	Answer
• The decision aid makes it possible to compare the positive and negative features of the available options.	Yes
• The decision aid shows the negative and positive features of the options with equal detail.	Yes
• The decision aid compares probabilities (e.g. chance of a disease, benefit, harm, or side effect) of options using the same denominator.	NA
• The decision aid (or available technical documents) reports funding sources for development.	Yes
• The decision aid reports whether authors of the decision aid or their affiliations stand to gain or lose by choices people make after using the decision aid.	Yes
• The decision aid includes authors/developers' credentials or qualifications.	Yes
• The decision aid reports the date when it was last updated.	Yes
• The decision aid (or available technical document) reports readability levels.	Yes
• The decision aid provides references to scientific evidence used.	Yes

PDA overview

*Making quality decisions
about primary breast
augmentation surgery*

design overview

Content blocks are color-coded for easy identification of the relevant decision

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How should I prepare for decision-making?	Is plastic surgery right for me?	Should I have breast augmentation surgery?	What questions should I ask my plastic surgeon?	What are my next steps?
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Provides guidance for using the PDA

Format

PDF, can be viewed digitally or as a printed document.

Designed to replace traditional informed consent documents for primary breast augmentation surgery.

PDA structure

context-oriented to the relevant decision rather than *content-oriented* like traditional informed consent documents

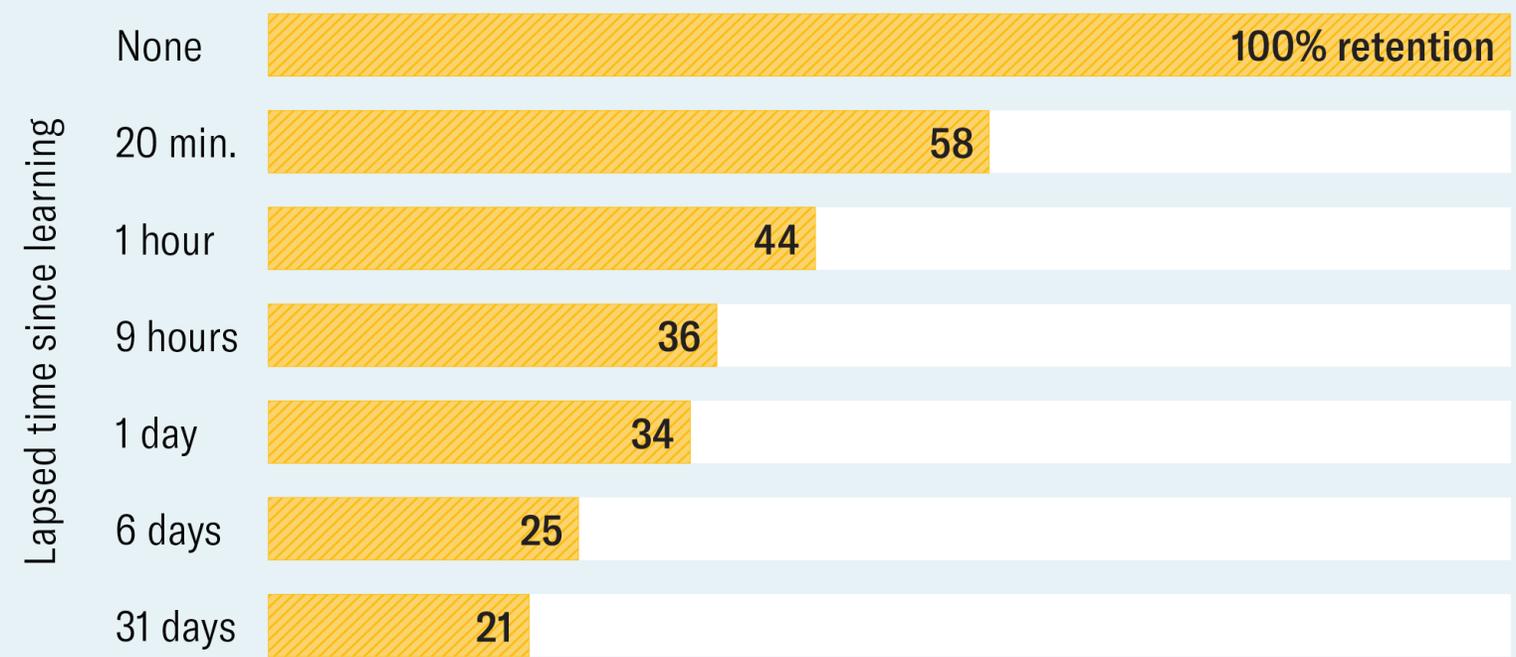
- organized into useful chunks along the decisional timeline
- information is learned as it is needed and can be immediately applied to the patient's actual decision-making

Each section [content block] is guided by an overarching question & includes:

- the relevant decision or decisions necessary to consider;
- the essential information needed to make a decision;
- details about why the information is important or how it should specifically inform the patients' decision-making.

The Forgetting Curve

If new information isn't applied, we'll forget about 75% of it after just six days.



Source: Hermann Ebbinghaus
From: "Where Companies Go Wrong with Learning and Development," by Steve Glaveski, 2019



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- screening criteria
- expert consensus
- crowdsourcing
- quality criteria

Identifies the target user.

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Highest level of school completed: 92% report at least some college, with 53% having an undergraduate degree or higher; 0% report completing < grade 9.

Use plain language?

- Is written at a level that can be understood by the majority of patients in the target group (10.3)
- Is written at a grade 8 equivalent level or less according to readability score [SMOG or FRY]*(10.4)

Procedure-specific core information set defined by relevant clinical experts

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Helps patients recognise a decision needs to be made (12.1)

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Level of detail, preferred timing, format and presentation of information defined by the relevant patient experts



legend explained for annotations



- Minimum standards for **screening** and **certification** published by the National Quality Forum (NQF).
- Detailed criteria for evaluating the **quality** of PDAs is published by the International Patient Decision Aid Standards (IPDAS) Collaboration.
- Hagopian CO, Hagopian TM, Wolfswinkel EM, Ades TB, Stevens WG **An expert consensus study for informed consent in primary breast augmentation surgery** [accepted 2020-08-13 for publication in *Aesthet Surg J*].
- Hagopian CO, Hagopian TM, Wolfswinkel EM, Ades TB, Stevens WG. **Behaviors and perspectives of women considering primary breast augmentation surgery relevant to decision-making and informed consent** [unpublished manuscript; not yet submitted for peer-review].

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Level of detail, preferred timing, format and presentation of information defined by the relevant patient experts



-  quality criteria
-  expert consensus
-  crowdsourcing

How should I prepare for decision-making?

- Know what is expected of me in decision-making
- Know what information to trust about plastic surgery
- Verify my surgeon is board-certified or eligible by the American Board of Plastic Surgery

Why is it important for me to actively participate in decision-making?

My plastic surgeon cannot read my mind to know what I do and do not want. Actively participating in decision-making means I need to know and clearly communicate with my plastic surgery care team:

- my specific concerns and goals for the result I want to achieve
- my values based on what risks and benefits matter most to me

Making sure my plastic surgeon and I have a clear understanding of my goals, values, and preferences can **reduce my risk of being unhappy with my surgical results.**

Helps patients to understand that values affect decision (12.4)

How do I know what information to trust when reading about plastic surgery?



- 5 key quality checks for appraising health information:**
1. **Author and qualifications.** Who wrote the information? Are qualifications listed describing why they are credible to speak on the topic?
 2. **Up-to-date.** Is a “date last reviewed” provided? Is the date within the past year?
 3. **Evidence-based.** Is a reference list included to the sources of evidence used to support the information? Are the sources credible?
 4. **Unbiased.** Are both pros and cons discussed equally? Does the author or publisher have a financial, or other, conflict of interest in how you use the information or your ultimate decisions? If so, is the conflict(s) disclosed?
 5. **Useful.** Does the information answer your question? Does it make sense? Can you easily apply what you have learned to your decision-making?

Consider using the HONcode eGuide for Health Consumers [website evaluation tool](#).

e-health literacy skills

- Use the American Board of Plastic Surgery (ABPS) website [surgeon search tool](#) to verify board certification status
- Review [FAQs](#) about board certification

A **board-eligible** plastic surgeon has successfully completed the required training in plastic surgery (residency) and has an approved application by the ABPS to enter the board-certification process.

How should this inform your decision-making?

- Surgeon technique and judgement can increase or decrease your risk of complications.
- If your surgeon is **not** board-certified or board-eligible by the American Board of Plastic Surgery, he or she may **not** have completed the pre-requisite training needed to safely perform plastic surgery.

“Perhaps the biggest risk comes when the unsuspecting patient is operated by an unqualified surgeon” (free-text)



e-health literacy

“...patients who have **access to high-quality evidence and health information**, and who also possess **e-health literacy skills to make sense of it**, can most meaningfully engage in shared decision making about their care.”

Davidson S, Weberg D, Porter-O'Grady T, Malloch K. *Leadership for Evidence-Based Innovation in Nursing and Health Professions* (p118). Jones & Bartlett Publishers;2016.

- expert consensus
- crowdsourcing
- quality criteria

Is plastic surgery right for me?

- Understand the general risks of surgery
- Consider factors that increase my risk of surgery and how I can reduce my risks

All surgery has important risks to consider. Some risks are general to surgery and others are specific to the type of surgery. The information presented in this patient decision aid does not include all possible risks, but rather the risks considered essential for all patients to understand before undergoing primary breast augmentation surgery.

General risks of surgery include **anesthesia risks, deep vein thrombosis (DVT) and pulmonary embolism (PE).**

Risk factors	<ul style="list-style-type: none"> • Smoking, or having a history of smoking, increases your general risk of surgery. • Carefully review your medical and social history with your plastic surgery care team to identify and address any potential risk factors that may impact the safety of your surgery and your ultimate cosmetic result.
Learn more about common risk factors, signs and symptoms, and how to prevent deep vein thrombosis (DVT) and pulmonary embolism (PE).	

Free-text comments described risks as being either general or dependent based on the individual patient, surgeon, or specific decision

Free-text comments repeatedly mentioned anesthesia and DVT/PE as two essential general risks of surgery

Should I have breast augmentation surgery?

- Clarify my cosmetic concerns, goals, and preferences
- Set realistic expectations for breast augmentation surgery and implants
- Identify the decisions, options, and what matters most to me when weighing the pros & cons

Why am I considering breast augmentation surgery?

Work through the following questions to clarify your cosmetic breast concerns, goals, and preferences.

What are my cosmetic breast concerns? Check all that apply to you.

My breasts are:

<input type="checkbox"/> Too small	<input type="checkbox"/> Not as firm as when I was younger
<input type="checkbox"/> Not proportionate with my body	<input type="checkbox"/> Not as full as when I was younger
<input type="checkbox"/> Deflated after pregnancy or breastfeeding	<input type="checkbox"/> Other cosmetic breast concern or concerns (please specify): _____
<input type="checkbox"/> Uneven	

What goals do I hope to achieve with primary breast augmentation? Check all that apply to you.

<input type="checkbox"/> Have a more balanced figure	Feel more:
<input type="checkbox"/> Increase the size of my breasts	<input type="checkbox"/> Attractive
<input type="checkbox"/> Make my breasts more symmetrical	<input type="checkbox"/> Confident naked
Restore volume:	<input type="checkbox"/> Feminine
<input type="checkbox"/> Lost with aging	<input type="checkbox"/> Confident in how clothes fit
<input type="checkbox"/> After weight loss	<input type="checkbox"/> Other (please specify): _____
<input type="checkbox"/> After pregnancy or breastfeeding	

Patients describe reasons for considering primary breast augmentation in terms of both goals they want to achieve and concerns they want to address

Suggest ways for patients to share what matters most with others (4.3)



Clarifies patient values for outcomes of options by:

describing the features of options to help patients imagine the physical and/or social and/or psychological effects;

and/or asking patients to consider or rate which positive and negative features matter most to them.

What are my preferences for how I want my breasts to look & feel after surgery?

How **full** do I want my breasts to **look** after breast augmentation?

Check your **preference**:



Source: Adapted from William P. Adams Jr. MD 2019 "Breast Education Guide & Preferences"

How **natural** do I want my breasts to **feel**?

Check how much it matters to you that your implants **feel natural**:

Not **important** **Very important**
 ① ② ③ ④ ⑤ ⑥ ⑦



It may be helpful to review **before-and-after photos** to get a general idea of what you do and do not like. Look for a before-and-after gallery on your plastic surgeon's website or ask their office. Choose photos of results with a similar body type to you.

I have a photo example of what I want my breasts to look like after surgery: Yes No

What do I need to know when deciding if breast augmentation surgery is right for me?

Check items that you feel are most important to your decision-making process.

General risks of breast augmentation surgery include:

Bleeding, hematoma (a collection of blood), and infection	
Potential consequences	<ul style="list-style-type: none"> • May require additional surgery (reoperation) • Reoperations have additional risks. There are certain situations that require implants to be removed but not replaced. • Complications following surgery may not be covered by your health insurance.
How to reduce your risk	<ul style="list-style-type: none"> • Follow your plastic surgeon's pre- and postoperative instructions and activity restrictions. • Identify and address with your plastic surgery care team any risk factors specific to your medical history and lifestyle.
Change in nipple sensation including increased, decreased, or complete loss of sensation	
Potential consequences	<ul style="list-style-type: none"> • Nipple sensation changes may be temporary or permanent.

expert consensus
crowdsourcing

Need to inform there are known and unknown risks of implants (free-text)

BII did not meet consensus threshold but several free-text entries mentioned the need for its inclusion

There are known and unknown risks of breast implants.

A **known, or true, risk** is defined and supported by scientific evidence of causation. A key example is *breast-implant associated anaplastic large cell lymphoma (BIA-ALCL)* with textured implants. An **unknown, or poorly understood, risk** is **not** supported by scientific evidence of causation, but may still be a consideration for some patients. These risks **may or may not** be defined. For example, a wide spectrum of *systemic symptoms* have been reported by some women with both saline and silicone, smooth and textured surfaced breast implants. The true relationship between breast implants and these systemic symptoms has yet to be scientifically defined.

Current research shows that silicone gel breast implants **do not** increase your risk of *autoimmune illnesses* nor *connective tissue diseases*. However, breast implant manufacturers are required to list them as possible risks in the directions for use of breast implants.

Breast implants are not lifetime devices

It is likely you will need additional surgery related to your implants at some point in your lifetime.

Continue to follow-up with your plastic surgeon as recommended for implant monitoring and maintenance and if you experience any implant-related issues or concerns.	
Expect future out-of-pocket expenses	<ul style="list-style-type: none"> Health insurance plans likely will not cover any expenses related to your breast implants, including for any complications. Available financial assistance programs include implant manufacturer warranties and surgeon-specific cosmetic complication insurance.
Long-term considerations	<ul style="list-style-type: none"> Breast implants may impact breast cancer surveillance. Continue routine screening as recommended by your doctor.
Reoperations for implant maintenance is expected and is not a complication.	

68% prefer the format for presenting information about what to expect over the long-term after surgery (text description)

What implants can and cannot do.

Implants increase breast size and expand the breast envelope. Minimal breast ptosis (drooping or sagging) can often be corrected with implants, but implants will **not** correct significant skin laxity or severe ptosis. There may be alternative or combination procedures for you to consider.

<ul style="list-style-type: none"> A breast lift (mastopexy) may be appropriate to consider to reshape or lift the breasts. While not interchangeable with breast implants because the results are less predictable, fat grafting may be a reasonable alternative or addition to implants to add breast volume. Not having surgery is an option. Padded bras and inserts can be used to give the appearance of larger breasts without surgery.
Alternative or combination procedures have different or additional risks to consider beyond what is presented in this decision aid.

When asked how respondents expect implants will change their breasts:

- larger (81%)
- lifted (80%)
- different shape (72%)
- unsure (1%)

Your cosmetic result is directly related to your anatomy.

Understanding the limitations of your specific breast and chest wall characteristics is a key component of good preoperative planning and can help you to set realistic expectations.

Asymmetry	<ul style="list-style-type: none"> 100% of women have differences between their breasts (such as in size, nipple position, inframammary fold position, or chest wall anatomy). These differences will not be corrected, and breasts will never match.
Cosmetic dissatisfaction	<ul style="list-style-type: none"> You can expect that your results will change over time as your body changes, for example with pregnancy, weight change, and normal aging. Satisfaction with your implants may change over time and is not a complication.

56% prefer the format for presenting information about what results to expect (text description)

Need to clearly differentiate between complications and expectations (free-text)



- screening criteria
- certification criteria
- quality criteria
- crowdsourcing

Explicitly states the decision under consideration.

Describes the options available for the decision, including nontreatment when appropriate.

Provides a balanced presentation of options.

Implant style decisions		For each option, check <input checked="" type="checkbox"/> if you have a preference.		
Decision #1: Implant fill				
Options:	<input type="checkbox"/> Silicone	<input type="checkbox"/> Saline		
FDA-approved for:	Women ages 22 and older	Women ages 18 and older		
Key risk of implant rupture or deflation	Risk of "silent" rupture, meaning you and your surgeon will likely not be able to tell the implant is ruptured just by looking at or feeling the implant.	Saline implants will deflate partially or completely if ruptured, so you will know by looking at or feeling implants.		
Why is this important?	<ul style="list-style-type: none"> Additional monitoring is needed with imaging tests, such as MRI or ultrasound, periodically over the lifetime of the implant. The cost of imaging tests will most likely be out-of-pocket. 	<ul style="list-style-type: none"> No additional monitoring is needed beyond following up with your board-certified plastic surgeon. 		
There is more than one type of silicone and saline implants.	Silicone options		Saline options	
	<p>There are a range of silicone gel types and styles that range in cohesivity, or consistency, of the implant that vary by manufacturer.</p> <p><input type="checkbox"/> Less cohesive silicone gel implants feel more natural; the implant volume is positional, similar to the behavior of a natural breast.</p> <p><input type="checkbox"/> Highly cohesive, form-stable, implants maintain their shape.</p>		<table border="1"> <tr> <td><input type="checkbox"/> Traditional Implant is placed deflated and then filled with sterile saline solution, allowing for a smaller incision and minor volume adjustment</td> <td><input type="checkbox"/> Structured An inner and outer shell structures how the sterile saline solution fills the implant for a different feel compared to traditional saline</td> </tr> </table>	<input type="checkbox"/> Traditional Implant is placed deflated and then filled with sterile saline solution, allowing for a smaller incision and minor volume adjustment
<input type="checkbox"/> Traditional Implant is placed deflated and then filled with sterile saline solution, allowing for a smaller incision and minor volume adjustment	<input type="checkbox"/> Structured An inner and outer shell structures how the sterile saline solution fills the implant for a different feel compared to traditional saline			
Implant style options vary by manufacturer.	<input type="checkbox"/> Sientra <input type="checkbox"/> Mentor <input type="checkbox"/> Allergan	<input type="checkbox"/> Mentor <input type="checkbox"/> Allergan	<input type="checkbox"/> Ideal Implant	
Why is this important?	<p>Different implants have different risks. Implant manufacturers use different terms to describe their portfolio of implant styles and different methods for collection and reporting of risk data. Specific risk probabilities are not listed in this decision aid because available data does not allow for direct comparison of different implants and their risks across manufacturers.</p> <p>Review current FDA: Labeling for Approved Breast Implants to learn more.</p>			
Key benefit	Discuss with your plastic surgeon which implant fill option will best meet your desired preference for how you want your breasts to feel .			
Decision #2: Implant shape				
Options:	<input type="checkbox"/> Anatomic	<input type="checkbox"/> Round		
Key risk of implant rotation or displacement	<ul style="list-style-type: none"> Risk of implant <u>rotation or displacement</u> Anatomic implants are textured to reduce this risk. 	<ul style="list-style-type: none"> No concern of implant <u>rotation</u>, you will not be able to tell any difference. There is a possibility for round implants to become <u>displaced</u> or flipped in relation to the pocket. 		
Why is this important?	If a breast implant rotates or becomes displaced your breasts will change shape or become noticeably asymmetric and may require surgical correction.			
Key benefit	Discuss with your plastic surgeon which implant shape option will best meet your desired preference for how full you want your breasts to look .			

>50% prefer the format for presenting information about:

- general description of how breast augmentation surgery is performed (**video**)
- available implant options (**physical models in the office**)

Describe uncertainty around probabilities (3.4)

screening criteria

crowdsourcing

Decision #3: Implant shell

Options:

Key risk of breast implant associated anaplastic large cell lymphoma (BIA-ALCL)

Why is this important?

Key benefit

Textured

- All textured implants have an association with ALCL.
- There is an increased risk with high degree of texturing and lower risk with lower degree of texturing.
- Macrot textured devices carried the highest risk and are now no longer available.

Smooth

- No known risk of BIA-ALCL with smooth implants

Key benefit

This decision is related to Decision #2: Implant shape. Discuss with your plastic surgeon your desired preference for how **full** you want your breasts to **look** and whether textured or smooth implants are right for you.

Describes the positive features of each option.

Level of detail >80% believe it is necessary to know before making a decision: a list of the risks, potential consequences, the likely signs & symptoms, any risk reduction strategies, and what to do if the complication occurs

How do I choose the right size?

Sizing methods

Key risk of reoperation for cosmetic reasons

Advisory of increased risks with oversized implants. Risk of cervical spine changes, back/neck pain.

 Learn more about the [risks and complications of breast implants](#). This resource from the FDA includes a glossary of risks and photo examples of capsular contracture and saline implant deflation as well as links to additional information and resources about breast implants.

Notes and additional quality information resources:

screening criteria
 expert consensus
 crowdsourcing

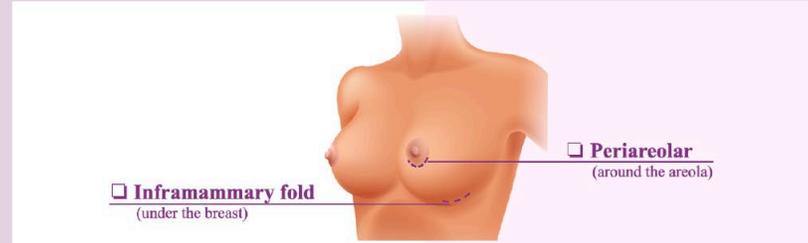
Only the IMF and PA incision options met criteria for consensus

Surgical approach decisions For each option, check if you have a preference.

Decision #1: Incision location*

Options:

*Your plastic surgeon may discuss other incision locations than the 2 options described here if appropriate for you, such as transaxillary (through the armpit).



Key risk of capsular contracture

Decreased risk of capsular contracture with **inframammary fold incision**

Increased risk of capsular contracture with **periareolar incision**

Why is this important?

- Capsular contracture can lead to hardening of the affected breast, pain, and an unnatural appearance; may require additional surgery depending on severity.
- Signs and symptoms of capsular contracture may mimic other issues, such as implant displacement, BIA-ALCL, or ptosis. Reducing the risk of capsular contracture can help to avoid confusion or unnecessary alarm about other risks.

Decision #2: Placement plane (pocket selection)

Options:

Key risk of capsular contracture

Implant texturing may reduce this risk

Key risks of seeing or feeling the implant in a way that is not cosmetically desirable and implant wrinkling or rippling

Why is this important?



Subpectoral (under the chest muscle)

Decreased risk of capsular contracture

There is no difference in risk of capsular contracture with textured or smooth implants when placed subpectoral

Breast animation deformity may occur with subpectoral placement. The degree of implant distortion depends on the thickness and position of your chest muscle and the amount of muscle coverage of the implant.

- Subpectoral placement may not be possible if you are a bodybuilder.
- Discuss your lifestyle and activity level with your plastic surgeon.

Subglandular (over the chest muscle)

May have **increased risk** of capsular contracture

Using textured implants may help reduce the risk of capsular contracture when placing implants subglandular

Your skin and breast tissue characteristics impact the likelihood of seeing or feeling the implant in a way that is not cosmetically desirable, including implant wrinkling or rippling.

- This risk may be increased if you have thin skin or breast tissue.
- Discuss how your skin, breast and chest anatomy will impact your ultimate result with your surgeon.

>60% prefer the format for presenting information about:

- options for implant placement and incision location (**photos**)
- risks of breast augmentation surgery (**text description**)

Describes the negative features of each option.

Applies the core information set as a reference standard for assessing a patient's background knowledge

Helps to focus consultations on what patients **need** to know rather than on what they **already** know

What else do I need to prepare for decision-making?

Find out how well this decision aid helped you learn the key facts. Check the best answer.

1. The risk of breast implant associated anaplastic large cell lymphoma (BIA-ALCL) is associated with:
 Textured implants Smooth implants I am not sure
2. Unless I experience a complication, it is unlikely that I will need to have another surgery related to my breast implants during my lifetime.
 True False I am not sure
3. My plastic surgeon and I may not be able to tell if ___ implants rupture just by looking at or feeling my breasts.
 Saline Silicone Both saline and silicone I am not sure
4. After undergoing primary breast augmentation surgery, additional **out-of-pocket** costs may include: (Check all that apply)
 Image screening tests for implant monitoring, such as MRI or ultrasound
 Reoperation(s), one or more repeat surgery related to my breast implants
 There are no further expenses beyond my initial breast augmentation surgery, everything else is covered by insurance and the breast implant warranty
 I am not sure
5. The true relationship between breast implants and a wide spectrum of systemic symptoms reported by some women with breast implants has yet to be scientifically defined.
 True False I am not sure
6. My board-certified plastic surgeon can correct any asymmetry I have with implants so that my breasts are symmetric after surgery.
 True False I am not sure
7. Capsular contracture is a risk of breast augmentation that can lead to what?

 I am not sure
8. If ___ implants rupture, my plastic surgeon and I will be able to tell by looking at or feeling my breasts.
 Saline Silicone Both saline and silicone I am not sure
9. How will implants change your breasts? (Check all that apply.)
 Make them larger Lift them Make them a different shape I am not sure

Check your answers for the key facts:

1. Textured implants, 2. False, 3. Silicone, 4. Image screening tests and reoperations, 5. True, 6. False, 7. Hardening of the affected breast, pain, and an unnatural appearance; commonly requires surgery, 8. Saline, 9. Make them larger.

expert consensus

crowdsourcing

Informed by questions respondents most commonly answered incorrectly

Questions are written to help patients **appreciate** and draw **correct inferences** about important risks and expectations

- certification criteria
- crowdsourcing
- quality criteria

Include tools [worksheet, question list] to discuss options with others (6.3)

Suggest ways to talk about the decision with a health professional (6.2)

Provides ways to help patients understand information other than reading [audio, video, in-person discussion] (10.5)

88% want a list of risks; risks are applied to the relevant decision

IPDAS quality items related to presenting outcome probabilities (3.1-3.13)

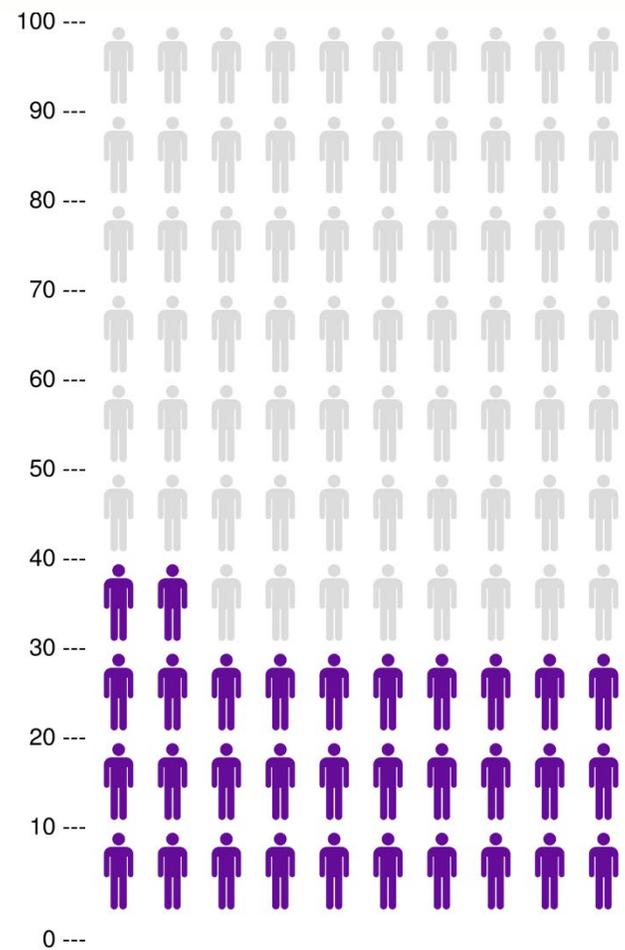


What questions should I ask my plastic surgeon?		
• Consultation guide		
	Key risks and considerations Check <input checked="" type="checkbox"/> what risks matter most to you	Notes
Am I a good candidate for plastic surgery?	General risks of surgery: <input type="checkbox"/> Anesthesia risks <input type="checkbox"/> DVT/PE	
	Do I have any specific risk factors in my medical or social history?	
Is breast augmentation the right decision to address my cosmetic concerns?	General risks of breast augmentation surgery: <input type="checkbox"/> Bleeding <input type="checkbox"/> Hematoma <input type="checkbox"/> Infection <input type="checkbox"/> Reoperation for complication <input type="checkbox"/> Reoperation requiring removal without replacement <input type="checkbox"/> Nipple sensation changes	
	<ul style="list-style-type: none"> • Should I consider any alternative or combination procedures to best address my cosmetic breast concerns? • If so, what different or additional risks do I need to know? 	
Which implants will best help me to achieve my goals?	How will my specific breast and chest wall anatomy and tissue characteristics impact my cosmetic result? Patient-dependent risks and tradeoffs: <input type="checkbox"/> Asymmetry (preexisting [persistent] or new) <input type="checkbox"/> Ability to see or feel the implant in a way that is not cosmetically desirable <input type="checkbox"/> Implant wrinkling or rippling	
	Implant styles vary by manufacturer, and different implants have different risks & benefits Implant-dependent risks and tradeoffs: <input type="checkbox"/> Implant rupture or deflation <input type="checkbox"/> BIA-ALCL <input type="checkbox"/> Capsular contracture <input type="checkbox"/> Implant rotation or displacement Is my activity level a concern? (such as body-building)	
What size is right for me?	Decision-dependent risks and tradeoffs: <input type="checkbox"/> Reoperation for cosmetic size exchange	
Are my goals realistic?	What results can I reasonably expect? Decision-dependent risks and tradeoffs: <input type="checkbox"/> Cosmetic dissatisfaction <input type="checkbox"/> Reoperation for cosmetic style exchange	
How likely are complications?	Complications are surgeon-specific. This icon array tool can help you and your plastic surgeon talk about risks that matter most to you.	

Currently print info, write a question list, and/or take notes during consult (free-text)

Provides key outcome probabilities, adopting risk communication principles.

icon array



 32 out of 100 people experience [risk] within [timeframe]

 68 out of 100 people don't experience [risk] within [timeframe]

Sample description:

[Risk] within [timeframe]

Description: [e.g., consequences, signs/symptoms, what to do if experience this complication, how to reduce risk]

What does the data show?

Blocks of 100 persons show a 'best estimate' of what happens to **100 people** following primary breast augmentation with implants over **[time frame]**.

Each person () stands for one person. The shaded areas show the number of people affected.

Data source: [numerator/denominator]

<http://clinician.iconarray.com>

A main reason patients seek consultation is to learn their next steps (free-text)

What are my next steps?

- Am I clear about what is expected of me and about what matters most to me?

crowdsourcing
quality criteria

Before scheduling surgery

1. Am I clear about what to expect before, the day of, and immediately after surgery?

- Postoperative expectations (e.g., pain) and restrictions (e.g., exercise)
- After surgery, you will be given a **Device Identification Card** that contains your implants unique identifier number. It is important to keep this card for your records because if you experience any issues with your implants this information should be shared with your health care provider and the implant manufacturer.
- I have received pre- and postoperative instructions from my plastic surgeon

2. What are my financial responsibilities, both now and in the future?

What am I responsible for <u>now</u> ?	<input type="checkbox"/> Quote for cost of surgery
What will I, or could I, be responsible for in the <u>future</u> ?	<input type="checkbox"/> Expected out-of-pocket costs associated with implant surveillance (silicone) and maintenance (all implants) <input type="checkbox"/> Possible out-of-pocket costs if I experience a complication following surgery
What <u>financial assistance</u> is available?	<input type="checkbox"/> Implant manufacturer warranty <input type="checkbox"/> Cosmetic complication insurance

>60% prefer the format for presenting information about financial responsibilities and what to expect immediately after surgery (recovery) (text description)

3. Find out how comfortable you feel about deciding.

	Yes	No
1. Do you know the benefits and risks of each option?	<input type="checkbox"/>	<input type="checkbox"/>
2. Are you clear about which benefits and risks matter most to you?	<input type="checkbox"/>	<input type="checkbox"/>
3. Do you have enough support and advice to make a choice?	<input type="checkbox"/>	<input type="checkbox"/>
4. Do you feel sure about the best choice for you?	<input type="checkbox"/>	<input type="checkbox"/>

(The SURE Test © O'Connor & Légaré, 2008)

- If you answered 'No' to any of these, you are not ready to make a decision. Consider the following suggested activities to try based on your specific decision-making needs and discuss with your plastic surgery care team.

- Need more information?** Review the additional quality information resources linked throughout this decision aid, and ask your plastic surgery care team for additional resources specific to your informational needs:
- Unsure what matters most to you?** Work through this decision aid again with your plastic surgery care team, a trusted friend, family member, or significant other.
- Need more support?** List your support concerns and discuss with your plastic surgery care team:

- If you answered 'Yes' to all of these, you are ready to make a decision.

Provide steps to make a decision (6.1)



Confirm your decision

I have decided to **proceed** with primary breast augmentation surgery with the following specifications:

Fill:	Shape:	Shell:	Manufacturer:
<input type="checkbox"/> Silicone	<input type="checkbox"/> Round	<input type="checkbox"/> Smooth	<input type="checkbox"/> Sientra <input type="checkbox"/> Ideal Implant
<input type="checkbox"/> Traditional saline	<input type="checkbox"/> Anatomic	<input type="checkbox"/> Textured	<input type="checkbox"/> Allergan <input type="checkbox"/> Mentor
<input type="checkbox"/> Structured saline			Style #:

Placement:	Incision location:	Size:	Other specification (if applicable):
<input type="checkbox"/> Subpectoral	<input type="checkbox"/> IMF	Left: _____ cc	_____
<input type="checkbox"/> Subglandular	<input type="checkbox"/> Periareolar	Right: _____ cc	_____

I have decided to **decline** primary breast augmentation surgery.

Considering your decisions selected above, please answer the following questions:

	Strongly Agree	Agree	Neither Agree nor Disagree	Disagree	Strongly Disagree
1. I feel I have made an informed choice.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. My decision shows what is important to me.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. I expect to stick with my decision.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. I am satisfied with my decision.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

(Effective Decision Subscale of the Decisional Conflict Scale © AM O'Connor, 1993, revised 2005)

Patient Acknowledgement of Informed Consent

- I confirm my decision and voluntarily give my consent to undergo **primary breast augmentation surgery** with the specifications detailed on this form.
- I authorize _____ and assistants to perform the procedure.
- I understand and accept the possibility of unforeseen circumstances that require other procedures not described on this form. I voluntarily give my consent and authorize my surgeon and assistants to perform such procedures as deemed necessary based on the professional medical judgement of my surgeon to save my life or to prevent serious harm to my health.
- I confirm my acceptance and voluntarily consent to be photographed or recorded before, during, and after surgery for the purposes of medical documentation.
- I authorize the release of my protected health information for the purposes of medical device registration and registry reporting.
- I actively participated in a shared decision-making informed consent process with my plastic surgeon and plastic surgery care team as demonstrated in this decision aid and informed consent workbook.

PATIENT SIGNATURE PATIENT PRINTED NAME DATE

Surgeon Acknowledgement of Informed Consent

I confirm my agreement with the decision detailed above and agree to perform the procedure as authorized.

SURGEON SIGNATURE SURGEON PRINTED NAME DATE



certification criteria

quality criteria

Content last reviewed: 2020-08-16. **Review/update policy:** Annually.

Author:	Chelsea O. Hagopian, DNP ^a (nursing and shared decision-making)
Research committee:	Teresa B. Ades, DNP (nursing and health literacy); Thomas M. Hagopian, MD, Erik M. Wolfswinkel, MD, and W. Grant Stevens, MD (plastic surgery)
Expert medical review:	Laurie A. Casas, MD, FACS ^b , Melinda Haws, MD ^c , William P. Adams Jr., MD ^a , Caroline Glicksman, MD, MSJ ^d , Michael Bradley Calobrace, MD, FACS ^a , Patricia McGuire, MD ^e , Clark Schierle, MD, PhD, FACS ^a , Kent K. Higdon, MD ^a (plastic surgery)
Disclosures:	^a No disclosures; ^b Sientra Post Approval Study Clinical Investigator Since 2012; ^c Educator Sientra, business advisory board realself, Allergan collaboration; ^d Medical Director Motiva Breast Implant Clinical Trial; ^e Consultant Allergan, Establishment Labs, Hans Biomed Clinical investigator Motiva US FDA Clinical trials
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Developer contact information For any questions or concerns about the content or development of this patient decision aid, please contact the author directly at chelsea.hagopian@alumni.emory.edu.

Development and design[†]
 Hagopian CO, Hagopian TM, Wolfswinkel EM, Ades TB, Stevens WG. Development and preliminary evaluation of a patient decision aid to replace traditional informed consent documents for primary breast augmentation surgery [unpublished manuscript; not yet submitted for peer-review].

[†]An overview of the development process and design with recommendations is included as an appendix for convenience of review.

Content informed by
 Hagopian CO, Ades TB, Hagopian TM, Wolfswinkel EM, Stevens WG. Attitudes, beliefs, and practices of aesthetic plastic surgeons regarding informed consent. *Aesthet Surg J.* 2020;40(4):437-447.

Hagopian CO, Hagopian TM, Wolfswinkel EM, Ades TB, Stevens WG. An expert consensus study for informed consent in primary breast augmentation surgery [accepted 2020-08-13 for publication in *Aesthet Surg J*].

Hagopian CO, Hagopian TM, Wolfswinkel EM, Ades TB, Stevens WG. Behaviors and perspectives of women considering primary breast augmentation surgery relevant to decision-making and informed consent [unpublished manuscript; not yet submitted for peer-review].

Breast Device Collaborative Community (BDCC). Jamee Cook, Raylene Hollrah, Mindy Haws MD, Lisa Schlager, Pat McGuire MD, Andrea Pusic MD, Madris Tomes, Debra Johnson MD, William P. Adams Jr. MD, Rosalyn d'Incelli, Kourtney Cavallio, Raina Dauria, Robert Hamas MD. Implant Checklist Submitted FDA 10-2019, 2-1-2020. This checklist was used to cross-check the PDA for content comprehensiveness. BDCC functions to bring together stakeholders with diverse perspectives to address challenges and concerns surrounding breast implants and related topics for the FDA.

Additional content contributors
 The following contributors are board-certified plastic surgeons who participated in a follow-up survey of active members of the American Society for Aesthetic Plastic Surgery (ASAPS) exploring current practices for confirming patient comprehension before primary implant-based breast augmentation surgery conducted to further inform the content of this decision aid. Additional survey participants chose to remain anonymous.
 Benjamin Van Raalte, MD; David J. Levens, MD; Robert Grant, MD; Brian J Lee, MD; Elsa Raskin, MD; Scott Greenberg, MD; William Bull, MD; Jubert Sanches, MD; Melinda Haws, MD; Diane Colgan, MD; Winston Santos, MD; Robert Zubowski, MD; Paul Weiss, MD; Kent V Hasen, MD; Hisham Seify, MD; Tiffany McCormack, MD; Thomas George Fiala, MD; Mike Burgdorf, MD; Michael Bogdan, MD; Mark Jewell, MD; Susan MacLennan, MD; Tracy Pfeifer, MD; Emily Hartmann, MD; Roberta L Gartside, MD

Provides a publication date.

Includes developers' credentials / qualifications (1.1)

Provides information about the update policy and next expected update.

Provides information about competing interests and/or policy.

Provides information about the funding sources used for development.

Provides information about the patient decision aid development process, including information about participation from target users and health professionals.

Contains content based on a rigorous and documented evidence synthesis method.

Uses evidence from studies of patients similar to those of target audience (11.6)



Download the PDA at:
www.surgery.org/pda

Making quality decisions about primary breast augmentation surgery

A decision aid to support informed choices that reflect best evidence and what matters most to you

What is the purpose of this decision aid?

This decision aid is designed to prepare you for decision-making and to facilitate shared decision-making with your plastic surgeon, by helping to:

- introduce the decisions necessary to consider before primary breast augmentation surgery,
- educate you on the essential information you need to know to make each decision, and
- identify your goals, values, and preferences relevant to each decision and clearly communicate them to your plastic surgery care team.

Who should use this decision aid?

This decision aid is for you if:

- You are a woman age 18 or older, and
- You are considering primary breast augmentation (enlargement) surgery with saline or silicone implants, for cosmetic reasons.
- *Primary* breast augmentation means you have not previously had a breast augmentation surgery.

This decision aid is not for you if:

- You are under the age of 18, or
- You are considering breast implant surgery for:
 - reconstructive purposes after breast cancer surgery,
 - revision of a previous breast augmentation surgery, or
 - gender affirming male-to-female surgery.
- Breast implant surgery for reconstructive, revision, or gender affirming reasons have different or additional information essential for decision-making but not covered in this decision aid, including options, risks, benefits, expectations or limitations.

What content is and is not covered in this decision aid?

- This decision aid includes only the information considered essential for all patients to understand before surgery when considering primary breast augmentation surgery.
- This decision aid may not include information important to your individual decision-making process or relevant to your specific situation, such as information about certain treatment options, risks, or tradeoffs. **This decision aid is not a replacement for consultation with a plastic surgeon.**

How should I use this decision aid?

Use this decision aid before and throughout the consultation and informed consent process with your board-certified plastic surgeon. It is structured to help you answer the following questions:

How should I
prepare for
decision-making?

Is plastic surgery
right for me?

Should I have
breast augmentation
surgery?

What questions
should I ask my
plastic surgeon?

What are my
next steps?

thank
you

contact information

For more info, please contact me
directly at:

chelsea.hagopian@alumni.emory.edu
404-307-5004

www.chelseahagopian.com

early experiences using the PDA in practice





Thank you for your time.

Made Possible by an Educational Grant from Allergan Aesthetics

looking ahead

long term goals

scale-up & spread

research

effectiveness evaluation

long-term goals

scale-up

Interactive, defined as allows for user input (both patient and practice), web-based platform with:

- Foundational content to provide the general structure of the PDA (e.g., How to prepare..., Is plastic surgery right for me, etc.), and
- Procedure-specific content blocks.

Modifiable, to populate relevant procedure-specific content when the procedure block is selected.

spread

If prototype is acceptable to end-users (plastic surgeons and patients), the ultimate goal is to have a database of procedure-specific content blocks.

Apply the strategy of mass customization with buildable educational informed consent modules tailored to the specific needs of the individual patient.

Internet-based PDAs must meet additional quality criteria

PDAs use a variety of mediums to meet the needs and preferences of the target audience

Examples:

- For any decision
- Knee Osteoarthritis: Is it time to think about surgery?
- Advanced care planning
- Hidradenitis Suppurativa Patient Decision Aid

scale-up to web-based platform

- Decision summary
- Summary of patient pre-consultation learning & choice predisposition

Example of a PDA decision summary document:

- [Knee Osteoarthritis: Is it time to think about surgery?](#)
- [Summary of Clinical Priority and Patient's Preference for Total Joint Replacement](#)

Summary of patient input reasons considering surgery

This decision aid summary is for: **Hagopian, Chelsea** 1990-08-09 (29 y/o) Female

Making quality decisions about primary breast augmentation surgery

A decision aid to support informed choices that reflect best evidence and what matters most to you

Why I am considering breast augmentation surgery:

My cosmetic breast concerns: My breasts are too small and not proportionate with my body.

My goals for surgery: I hope to achieve a more balanced figure and to feel more confident in how clothes fit.

My preferences for how I want my breasts to look & feel after surgery:

How full I want my breasts to look after breast augmentation:

My preferred look:

minimal fullness

moderate fullness

maximum fullness

Source: Adapted from William P. Adams Jr. MD 2019 "Breast Education Guide & Preferences"

How natural do I want my breasts to feel: Not important: ① ② ③ ④ ⑤ ⑥ ⑦ Very important: ① ② ③ ④ ⑤ ⑥ ⑦

I do not have a photo example of what I want my breasts to look like after surgery.

My pre-consultation decision summary:

Implant style decisions	My preferred options:	
Decision #1: Implant fill	<input checked="" type="checkbox"/> Silicone	<input checked="" type="checkbox"/> Less cohesive
: manufacturer	<input checked="" type="checkbox"/> Sientra	
Decision #2: Implant shape	<input checked="" type="checkbox"/> Round	
Decision #3: Implant shell	<input checked="" type="checkbox"/> Smooth	
Surgical approach decisions	My preferred options:	
Decision #1: Incision location	<input checked="" type="checkbox"/> Inframammary fold (under the breast)	
Decision #2: Placement plane	<input checked="" type="checkbox"/> Subpectoral (under the chest muscle)	

This summary was prepared on: [date]

Summary of choice disposition

spread to other procedures

Format

Consider changing color coding to make all **foundational content a single anchor color** and procedure-specific content different colors, e.g., **primary breast augmentation [purple]**, **liposuction [blue]**

Making quality decisions about aesthetic plastic surgery



Title applicable to all aesthetic plastic surgery procedures

What else do I need to prepare for decision-making?
Find out how well this decision aid helped you learn the key facts. Check the best answer.

- The risk of breast implant associated anaplastic large cell lymphoma (BIA-ALCL) is associated with:
 Textured implants Smooth implants I am not sure
- Unless I experience a complication, it is unlikely that I will need to have another surgery related to my breast implants during my lifetime.
 True False I am not sure

Making quality decisions about aesthetic plastic surgery
A decision aid to support informed choices that reflect best evidence and what matters most to you

Purpose of this decision aid
This decision aid is designed to prepare you for each decision point before surgery and for what to expect after surgery, both immediately and long-term, by helping to:

- introduce the decisions to be made before undergoing primary breast augmentation and liposuction surgery,
- educate you on the essential information you need to know to make each decision,
- identify your goals, values, and preferences and clearly communicate them to your plastic surgery care team, and
- facilitate shared decision-making with your board-certified plastic surgeon.

This decision aid is for you if:

- You are a woman age 18 or older, and
- You are considering breast augmentation (enlargement) surgery with saline or silicone implants, for cosmetic reasons.

This decision guide is intended for use with primary breast augmentation, meaning you have not had a previous breast augmentation procedure.

- [additional or different specifications for consideration with liposuction surgery]

This decision aid is not for you if:

- You are under the age of 18, or
- You are considering breast implant surgery for:
 - reconstructive purposes after breast cancer surgery,
 - revision of a previous breast augmentation surgery, or
 - gender affirming male-to-female transgender top surgery.

Breast implant surgery for these indications carry different or additional information, including options, risks, benefits, expectations or limitations, essential for decision-making that are not specifically covered in this decision aid.

- [additional or different specifications for consideration with liposuction surgery]

How to use this decision aid
Use this decision aid before and throughout the consultation and informed consent process with your board-certified plastic surgeon. It is structured to help you answer the following questions:

How should I prepare for decision-making?	Is plastic surgery right for me?	Should I have primary breast augmentation surgery?	Should I have liposuction?	What questions should I ask my plastic surgeon?	What are my next steps?
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to be able to tell by looking at or feeling my
silicone I am not sure
additional **out-of-pocket** costs may include:
as MRI or ultrasound
to my breast implants
breast augmentation surgery, everything else
ranly
ers to a constellation of symptoms, such as
at have been reported by some women
It resolve if breast implants are removed.
 I am not sure
symmetries I have with implants so that my
 I am not sure
that can lead to what?
able to tell by looking at or feeling my breasts.
silicone I am not sure
at apply.)
em a different shape I am not sure
(Check all that apply.)
 I am not sure
(Check all that apply.)
 I am not sure
Check your answers for the key facts:
ing tests and reoperations, 5. True, 6. False,
ural appearance; commonly requires surgery,
8. Saline, 9. Make them larger.

Procedure-specific content populates appropriate sections

Anchor color (content common to all procedures)

Procedure-specific colors

research preliminary evaluation

<i>Evaluation type</i>	<i>Description</i>
Preliminary evaluation (alpha testing)	<p>Acceptability* to relevant medical experts:</p> <ul style="list-style-type: none"> ▪ PDA development process [Acceptability questions in Delphi surveys] ▪ PDA [The Aesthetic Society Informed Consent Task Force] <p>Quality of PDA [PDA reviewed against IPDAS quality criteria checklist]</p> <p>Fidelity of the development process [Adherence to development process model]</p>
Beta (field) testing	<p>Acceptability of PDA to primary end-users [acceptability questionnaire & 'Preparation for Decision Making' scale]:</p> <ul style="list-style-type: none"> ▪ clinicians involved in counseling patients on the index decision patients actively considering the index decision <p>Effectiveness [Hagopian et al., 2019, Figure 3. & IPDAS quality criteria checklist]</p> <ul style="list-style-type: none"> ▪ decision quality ▪ informed consent process
Comparative effectiveness evaluation	PDA compared to usual care (traditional informed consent documents)

**Consideration for further alpha testing with relevant patient experts (previously faced index decision)*

research effectiveness evaluation

<i>Evaluation type</i>	<i>Description</i>
Preliminary evaluation (alpha testing)	<p>Acceptability* to relevant medical experts:</p> <ul style="list-style-type: none"> ▪ PDA development process [Acceptability questions in Delphi surveys] ▪ PDA [The Aesthetic Society Informed Consent Task Force] <p>Quality of PDA [PDA reviewed against IPDAS quality criteria checklist]</p> <p>Fidelity of the development process [Adherence to development process model]</p>
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Comparative effectiveness evaluation	PDA compared to usual care (traditional informed consent documents)

**Consideration for further alpha testing with relevant patient experts (previously faced index decision)*

effective informed consent

realistically achieving **both** the ethical standards and legal requirements for informed consent **reliably** in practice without imposing additional burdens of time or expense to the clinician or patient

need for **measurable** outcomes
standard value equation employed in quality improvement of **value = quality / cost**¹

decision quality²

- informed
- meaningfully involved in decision-making
- decision concordant with patient values

cost

- time
- liability
- revision procedures
- materials & training

background

PDA research review

1. define best practice for informed consent
2. gap analysis to identify leverage point for improvement
 - traditional informed consent documents → replace with patient decision aids
3. design of a multiphase evidence-based **development process model** for creating IPDAS/NQF compliant PDAs to replace traditional informed consent documents for elective aesthetic procedures
4. pilot study focused on primary breast augmentation surgery with saline or silicone implants in collaboration with The Aesthetic Society

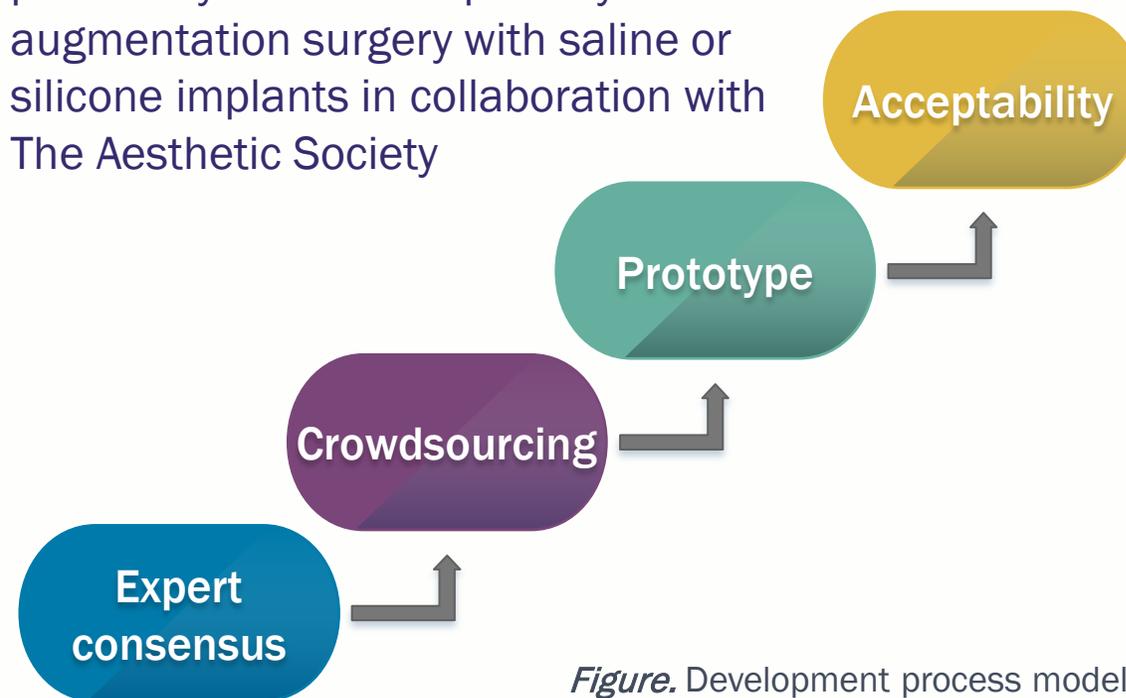


Figure. Development process model.

Provides information about the evidence sources used.

Additional references and hyperlinked content, by section

How should I prepare for decision-making?

Adams WP, Small KH. The process of breast augmentation with special focus on patient education, patient selection and implant selection. *Clin Plast Surg.* 2015;42(4):413-426. doi:10.1016/j.cps.2015.06.001

Adams WP, Culbertson EJ, Deva AK, et al. Macrot textured breast implants with defined steps to minimize bacterial contamination around the device: Experience in 42,000 implants. *Plast Reconstr Surg.* 2017;140(3):427-431.

Mioton LM, Buck DW, Gart MS, Hanwright PJ, Wang E, Kim JY. A multivariate regression analysis of panniculectomy outcomes: Does plastic surgery training matter? *Plast Reconstr Surg.* 2013;131(4):604e-12e.

Links

HONcodeHealth website evaluation tool (<https://www.hon.ch/HONcode/Patients/HealthEvaluationTool.html>)

American Board of Plastic Surgery (ABPS) verify certification surgeon search tool (<https://www.abplasticsurgery.org/public/verify-certification/VerifyCert?section=SurgeonSearch>)

American Board of Plastic Surgery (ABPS) FAQs about board certification (<https://www.abplasticsurgery.org/public/faqs/>)

Is plastic surgery right for me?

Fu RH, Toyoda Y, Li L, Baser O, Rohde CH, Otterburn DM. Smoking and postoperative complications in plastic and general surgical procedures: A propensity score-matched analysis of 294,903 patients from the national surgical quality improvement program database from 2005 to 2014. *Plast Reconstr Surg.* 2018;142(6):1633-1643. doi:10.1097/PRS.0000000000005008

Theocharidis V, Katsaros I, Sgouromallis E, et al. Current evidence on the role of smoking in plastic surgery elective procedures: A systematic review and meta-analysis. *J Plast Reconstr Aesthetic Surg JPRAS.* 2018;71(5):624-636. doi:10.1016/j.bjps.2018.01.011

Hanemann MS, Grotting JC. Evaluation of preoperative risk factors and complication rates in cosmetic breast surgery. *Ann Plast Surg.* 2010;64(5):537-540. doi:10.1097/SAP.0b013e3181cdabf8

Links

Centers for Disease Control and Prevention (CDC) What is Venous Thromboembolism? (<https://www.cdc.gov/ncbddd/dvt/facts.html>)

Should I have breast augmentation surgery?

Why am I considering breast augmentation surgery?

Mundy LR, HomaK, Klassen AF, PusicAL, Kerrigan CL. Normative data for interpreting the BREAST-Q: augmentation. *Plast Reconstr Surg.* 2017;139(4):846-853. doi:10.1097/PRS.0000000000003186

Links

William P. Adams Jr. MD 2019 Breast Education Guide & Preferences (<http://www.dr-adams.com/wp-content/uploads/2019/03/Breast-Education-Guide.pdf>)

What should I know when deciding if breast augmentation surgery is right for me?

Wan D, Rohrich RJ. Modern primary breast augmentation: Best recommendations for best results. *Plast Reconstr Surg.* 2018;142(6):933e. doi:10.1097/PRS.0000000000005050

Schwartz MR. Evidence-based medicine: Breast augmentation. *Plast Reconstr Surg.* 2017;140(1):109e. doi:10.1097/PRS.0000000000003478

certification criteria

Appendix

Table. Overview of PDA development process

<p>Preliminary work</p>	<p>(1) A needs assessment to define best practice of informed consent in the context of elective aesthetic procedures, explore decisional needs of relevant patients and clinicians, draft a working causal and program theory, and identify a leverage point for improvement; and</p> <p>(2) Design of a 4-phase development process model for creating PDAs that meet certification standards defined by the IPDAS Collaboration and the NQF to replace traditional ICDs for elective aesthetic procedures.</p> <p>Overarching theoretical, conceptual, and operational guidance drew from complexity science, quality improvement, knowledge translation and evidence-based practice. Additional theory and conceptual models inform each phase of the development process model.</p>
<p>Prototype development</p>	<p>Guided by the development process model:</p> <p><i>Phase 1: Expert consensus</i> of active members of The Aesthetic Society, board-certified plastic surgeons who specialize in aesthetic (cosmetic) plastic surgery [relevant clinical experts], using a modified Delphi process, a recognized method of establishing professional consensus, to define a core set of informed consent information considered essential for all patients to understand when considering primary breast augmentation surgery with implants [index decision].</p> <p><i>Phase 2: Consumer crowdsourcing</i> survey to learn the information behavior, e-health literacy skills, and knowledge gaps of adult (age 18+) females actively considering the index decision [target audience], and to define the level of detail needed to inform decision-making.</p> <p><i>Phase 3: Drafting of PDA prototype.</i> Initial drafting of the PDA was done following the first Delphi round. The PDA was refined with each iterative cycle of the development process. Final drafting of the PDA prototype followed the consumer crowdsourcing survey. Phases (1) and (2) helped to specify a search strategy for selecting evidence to further inform the final content of the PDA.</p> <p><i>Phase 4: Preliminary evaluation (alpha testing)</i> for (1) Expert medical review, (2) acceptability of (a) the PDA prototype to relevant medical experts and to relevant patient experts* [Breast implant patient advocates, have previously faced the index decision] and (b) the development process to relevant medical experts, (3) quality of the PDA prototype, and (4) fidelity of the development process.</p>
<p>Next steps</p>	<p>Beta (field) testing:</p> <p>Acceptability to primary end-users (clinicians involved in counseling patients on the index decision and patients actively considering the index decision), both clinicians internal and external to development process</p> <p>Effectiveness (decision quality, informed consent process)</p> <p>Comparative effectiveness evaluation: PDA compared to usual care (traditional ICD)</p>

**Readability scores*
 SMOG 11-12th grade
 FRY 8th grade

Follows plain language guidelines, to ensure understanding of people with low literacy and/or low health literacy skills.*

*Reports readability levels.**

**Manuscript reporting on the PDA development and preliminary evaluation not yet submitted for peer-review.*

Provides information about user testing with target patients and health professionals.



PDA, patient decision aid. IPDAS, International Patient Decision Aid Standards. NQF, National Quality Forum. ICD, informed consent document. *Proposed.

readability

SMOG score

- 11-12th grade

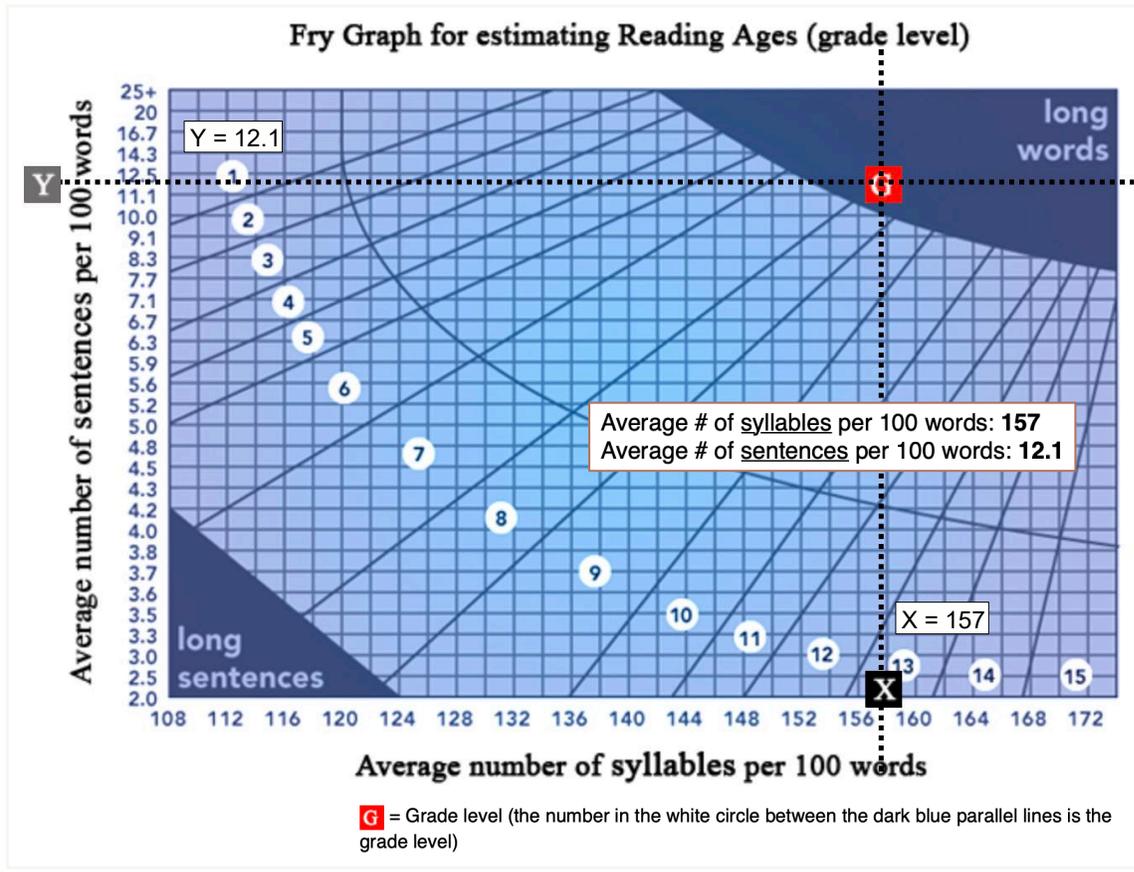
SMOG Grading

1. *Count 10 consecutive sentences near the beginning of the text to be assessed, 10 in the middle and 10 near the end. Count as a sentence any string of words ending with a period, question mark or exclamation point.*
2. *In the 30 selected sentences count every word of three or more syllables. Any string of letters or numerals beginning and ending with a space or punctuation mark should be counted if you can distinguish at least three syllables when you read it aloud in context. If a polysyllabic word is repeated, count each repetition.*
3. *Estimate the square root of the number of polysyllabic words counted. This is done by taking the square root of the nearest perfect square. For example, if the count is 95, the nearest perfect square is 100, which yields a square root of 10. If the count lies roughly between two perfect squares, choose the lower number. For instance, if the count is 110, take the square root of 100 rather than that of 121.*
4. *Add 3 to the approximate square root. This gives the SMOG Grade, which is the reading grade that a person must have reached if he is to understand fully the text assessed.*

readability

FRY score

- 8th grade



Source: <https://readabilityformulas.com/freetests/fry-graph.php>; based on: Fry E. A Readability Formula That Saves Time. *J Read.* 1968;11(7):513-578.