# Standardized Ultrasound Reporting for Ovarian-Adnexal Masses in Ontario

# **Explanatory** Notes

Version 1.0 (January 2025)

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## Development of the Ovarian-Adnexal Mass Ultrasound Reporting Tools

Ultrasound is the first line imaging modality for evaluating or detecting ovarian-adnexal (ovarian or fallopian tube) masses. It has high sensitivity, specificity, and cost effectiveness in the initial triage of ovarian-adnexal lesions<sup>1,2</sup>. However, there has been wide variation in the descriptive terms used in radiology reports characterizing ovarian-adnexal masses in Ontario, Canada. A classic example of a commonly used descriptive term is "complex cyst". The use of terms such as "complex cyst" is not recommended, as it is associated with ambiguity in diagnosis and lack of clarity about appropriate follow-up. It is recommended to use a standardized lexicon for describing ovarian-adnexal lesions to improve accuracy in assigning risk of malignancy and to promote appropriate patient management based on their level of risk. People with potentially malignant lesions should be referred to a gynecologic oncologist, while those with low-risk lesions could avoid unnecessary additional investigations and interventions such as ongoing surveillance ultrasounds, magnetic resonance imaging (MRI), and surgery.

The need for a consistent approach to ultrasound reporting of ovarian-adnexal masses was identified as a priority by the Ontario Gynecologic Cancers Advisory Committee and the Ovarian Cancer Diagnostic Pathway Map Working Group. In 2019, an Ovarian-Adnexal Mass Standardized Ultrasound Reporting Working Group was formed by circulating a call for Expressions of Interest for the improvement of radiology reporting in Ontario. Group members represented diverse practice settings and included radiologists, gynecologic oncologists, general gynecologists, ultrasonographers, sonographers and primary care providers interested in improving radiology reporting in Ontario. In this document, the term "ultrasonographer" means a Diagnostic Medical Sonographer, a healthcare provider who has met all the requirements for the specialty of diagnostic medical sonography, is registered with the College of Medical Radiation and Imaging Technologists of Ontario (CMRITO) and is authorized to practice in Ontario.

Evidence Search and Review Services at Ontario Health (Cancer Care Ontario) were engaged to identify existing descriptive lexicons, risk stratification guidelines, management recommendations and reporting templates for ultrasounds of ovarian-adnexal masses. Search methods and results are available in <u>Appendix A</u>.

The Working Group reviewed existing evidence, and a consensus was reached to adopt the American College of Radiology's (ACR's) Ovarian-Adnexal Reporting and Data System (O-RADS<sup>™</sup>) which includes a lexicon, and a risk stratification and management system based on ultrasound. Slight modifications to management recommendations were made to reflect the Ontario healthcare context, in accordance with an agreement between Ontario Health and the ACR. The most recent version of ACR's O-RADS<sup>™</sup>, v2022, has been adopted with minor variations (version v2022 can be found <u>here<sup>3</sup></u>). The companion system based on MRI has not been evaluated for the purposes of this working group. The O-RADS<sup>™</sup> **lexicon** is intended to describe all ovarian-adnexal masses initially identified on ultrasound including those identified in the context of people with acute/emergent symptoms or in those with an increased risk for malignancy. The O-RADS<sup>™</sup> **risk stratification and management system** is based upon an average risk adult (18 years and older) with no acute/emergent symptoms and no risk factors for ovarian cancer (e.g., such as a significant family history of ovarian cancer or

*BRCA* gene mutation). If these factors are present, management may vary from this system. The use of an accepted lexicon and a risk stratification and management system is anticipated to minimize the potential for classifying a classic benign lesion to a higher risk category while ensuring those at high risk for malignancy are appropriately referred to a gynecologic oncologist.

The Working Group developed documents to support implementation of O-RADS<sup>™</sup>, adapting guidance from the ACR for the Ontario healthcare context based on the working group's expertise. The documents were reviewed by the Working Group, Ontario Health (Cancer Care Ontario) disease site groups (e.g., the Gynecologic Cancers Advisory Committee), relevant program leadership and representatives, and additional clinical experts from across Ontario and Canada.

The end products of this work are:

- 1) Explanatory Notes (this document, which includes 2 and 3 below)
- 2) Sample Ultrasound Worksheet (page 21)
- 3) Radiologist Reporting Guidance and Cases with Sample Reports for Ontario (page 25)

Both the sample ultrasound worksheet and the radiologist reporting guidance for Ontario are based on the use of terms from the standardized O-RADS<sup>™</sup> ultrasound lexicon. The comprehensive assessment and image reporting guidance included in the explanatory notes are relevant to reporting radiologist and sonographers, but the broader clinical concepts are relevant to gynecologic oncologists, general gynecologists, and primary care providers.

### Key Resources for O-RADS<sup>™</sup>

The ACR's O-RADS<sup>™</sup> and all associated materials can be found at: American College of Radiology. American College of Radiology Committee on O-RADS<sup>™</sup> (Ovarian and Adnexal). Virginia USA: American College of Radiology; 2022. Available at: <u>https://www.acr.org/Clinical-Resources/Reporting-and-Data-Systems/O-RADS<sup>3</sup></u>

The O-RADS<sup>™</sup> ultrasound lexicon categories, terms, and definitions can be found at: American College of Radiology Committee on O-RADS<sup>™</sup> (Ovarian and Adnexal). O-RADS<sup>™</sup> ultrasound v2022 lexicon categories, terms, and definitions. American College of Radiology; 2023. Available at: <u>https://www.acr.org/-/media/ACR/Files/RADS/O-RADS/O-RADS-US-v2022-Lexicon-Terms-Table-</u> <u>2023.pdf</u><sup>4</sup>

A complete list of O-RADS<sup>™</sup> lexicon terms can be found at:

Andreotti RF, Timmerman D, Benacerraf BR, Bennett GL, Bourne T, Brown DL, et al. Ovarian-Adnexal reporting lexicon for ultrasound: a white paper of the ACR Ovarian-Adnexal reporting and Data System Committee. J Am Coll Radiol. 2018;15:1415–29. <u>https://doi.org/10.1016/j.jacr.2018.07.004</u><sup>5</sup>

A list of updates to O-RADSTM v2022 with rationale, can be found at: American College of Radiology Committee on O-RADS<sup>™</sup> (Ovarian and Adnexal). ACR O-RADS<sup>™</sup> US v2022 updates with rationale. American College of Radiology; 2022. Available at: <u>https://www.acr.org/-/media/ACR/Files/RADS/O-RADS/US-v2022/O-RADS-v2022-Updates.pdf</u><sup>6</sup> The following three webinars provide additional detail about the use of O-RADS<sup>™</sup> for ultrasound and are available for free. Completing the webinars can be used for Continuing Medical Education (CME) credits. The webinars can be found at:

- American College of Radiology. *O-RADS for ultrasound: why, what, when and how to use and report*. January 14, 2021. Accessed September 13, 2023. Available from: <u>https://www.youtube.com/watch?v=6\_SVuYPNExs</u><sup>7</sup>
- American College of Radiology. *O-RADS for ultrasound: case examples*. September 17, 2021. Accessed September 13, 2023. Available from: <u>https://www.youtube.com/watch?v=bzKOoO3-Luc</u><sup>8</sup>
- American College of Radiology. *O-RADS for ultrasound: frequently asked questions*. October 21, 2021. Accessed September 13, 2023. Available from: https://www.youtube.com/watch?v=41V1Fgc-080<sup>9</sup>

For a list of O-RADS<sup>™</sup> ultrasound frequently asked questions, please visit: <u>https://radssupport.acr.org/support/solutions/11000004077</u>

Another educational resource that may prove useful is O-RADS<sup>™</sup> Canada: <u>oradscanada.com</u>. This website is in development and is aimed at providing ongoing educational resources in utilizing O-RADS<sup>™</sup>.

## O-RADS<sup>™</sup> Risk Stratification and Management System: Ultrasound

The following section will deal with the risk stratification and management system for ovarian-adnexal lesions. It is useful to review the governing concepts prior to utilizing the system<sup>10</sup>.

#### O-RADS<sup>™</sup> Governing Concepts of the US Risk Stratification and Management System

- 1) O-RADS<sup>™</sup> ultrasound (US) applies to the ovaries, lesions involving (or suspected to involve) the ovaries and/or fallopian tubes, and paraovarian cysts, when the intent is to stratify risk of malignancy. Scenarios when O-RADS<sup>™</sup> does not apply include (but are not limited to): pelvic inflammatory disease, ectopic pregnancy, torsion of a normal ovary, and those lesions clearly identified as non-ovarian/non-tubal in origin (e.g., an exophytic or broad ligament myoma). If the origin of the lesion is indeterminate, options include CT and/or MRI.
- 2) Most non-visualized and all absent ovaries are classified as "O-RADS<sup>TM</sup>: not applicable". When only one ovary is visualized, it may be assessed per lexicon descriptors to obtain an O-RADS<sup>TM</sup> score. An exam may be considered "O-RADS<sup>TM</sup> 0: technically inadequate" when ovarian visualization is expected based on the indication for the exam but is not seen.
- 3) In cases of multiple or bilateral lesions, each lesion should be separately characterized, and management driven by the lesion with the highest O-RADS<sup>™</sup> score. Separate recommendations should be provided when management of one lesion is independent of the other.

- 4) Each patient will be categorized as pre- or postmenopausal with the post-menopause category defined as amenorrhea of greater than or equal to 1 year.
   Note: The recommendation diverges from ACR's O-RADS<sup>™</sup> v2022 as early and late menopause do not have clinical meaning in the Ontario healthcare context.
- 5) Some O-RADS<sup>™</sup> US management recommendations include the involvement of a physician whose practice includes a focus on ultrasound assessment of ovarian-adnexal lesions, denoted as an "ultrasound specialist". While there are no mandated requirements or guidelines that define such a specialist, potential qualifications include sufficient experience with the appearance of ovarian-adnexal pathology on US to improve the likelihood of correct diagnoses and participation in quality assurance activities related to ovarian-adnexal imaging.
- 6) Imaging assessment is based on transvaginal technique. Transabdominal imaging may add characterization and may suffice when transvaginal technique is not feasible or limited. When possible, orthogonal cine clips are strongly encouraged.
- 7) Single largest diameter of a lesion is used for risk stratification (scoring) and management. Reporting three dimensions is helpful to assess interval change, for which average linear dimension (L+W+H/3) should be used.
- 8) Lexicon terminology and lesion characterization apply to most lesions regardless of risk or symptoms. When uncertain about feature selection, (e.g., smooth versus irregular, color score, etc.) use the higher risk category to score the lesion.
- 9) Management recommendations should serve as guidance rather than requirements and are based on average risk and no acute/emergent symptoms. Individual case management may be modified by risk (e.g., personal or family history of ovarian cancer, known BRCA gene mutation, etc.), symptoms, other clinical factors, and professional judgement, regardless of the O-RADS<sup>™</sup> score.

#### Key Lexicon Terms and Definitions for Risk Stratification

# Table 1. O-RADS<sup>™</sup> Ultrasound Lexicon Key Terms and Definitions for Risk Stratification

Term	Sub-Term	Definition	Comments			
Major Categories o	Major Categories of Imaging Findings					
Physiologic (consist	tent with normal ovaria	n physiology)				
Follicle	Not applicable (N/A)	Simple cyst (unilocular, anechoic, smooth) ≤3 cm in premenopausal group	None			
Corpus luteum (CL)	N/A	Thick-walled cyst <b>typically</b> ≤3 cm, ± crenulated inner margins, ± internal echoes, with peripheral flow in premenopausal group	<ul> <li>May be solid appearing (no visible central fluid) with peripheral flow</li> <li>No internal flow</li> </ul>			

Term	Sub-Term	Definition	Comments		
Lesion (not physiologic)					
Unilocular cyst	Without solid component(s)	Cystic lesion with a single locule (no complete septa)	<ul> <li>± internal echoes, incomplete septa, wall irregularity &lt;3 mm in height</li> <li>Simple cyst: anechoic and smooth inner walls</li> <li>Non-simple cyst: smooth inner walls and internal echoes or incomplete septa</li> </ul>		
	With solid component(s)	As above and includes solid tissue ≥3 mm in height	None		
Bilocular cyst	Without solid component(s)	Cystic lesion with 2 locules (single complete septation)	± internal echoes, incomplete septa, or wall/septal irregularity (<3 mm in height)		
	With solid component(s)	As above and includes solid tissue ≥3 mm in height	None		
Multilocular cyst	Without solid component(s)	Cystic lesion with ≥3 locules (≥2 complete septations)	± internal echoes, incomplete septa, or wall/septal irregularity (<3 mm in height)		
	With solid component(s)	As above and includes solid tissue ≥3 mm in height	None		
Solid (≥80%)	N/A	Lesion with at least 80% solid tissue (based on echogenicity and echotexture)	<ul> <li>± internal vascularity</li> <li>May use term solid appearing if no internal vascularity</li> </ul>		
Size					
Maximum diameter	N/A	Largest diameter regardless or the plane in which it is obtained	Used for risk stratification		
Average linear dimension	N/A	(Maximum length + height+ width)/3	Used to assess interval change		
Solid or Solid-App	earing Lesions				
External Contour					

Term	Sub-Term	Definition	Comments
Smooth	N/A	Uniform/even outer margin	None
Irregular	N/A	Non-uniform/uneven outer margin	Includes lobulated
Posterior Acoustic	Features		
Shadowing	N/A	Broad or diffuse hypoechogenicity posterior to a lesion due to sound attenuation	<ul> <li>Associated with calcifications and fibromatous lesions</li> <li>Greatest relevance is for solid smooth lesions (as in fibromatous lesions)</li> <li>Differs from refractive artifact due to differences in attenuation by adjacent tissues, typically seen as linear shadowing from within or at edge of a lesion</li> </ul>
Cystic Lesions			
Inner Walls or Sept	tations		
Smooth	N/A	Uniform/even inner margin or septation	None
Irregular	N/A	Non-uniform/uneven outer margin	Focal wall or septal thickening <3 mm in height.
Calcifications	N/A	High-level echogenicity within wall associated posterior shadowing	Risk assessment based upon smooth or irregular margin
Internal Contents			
Contotions	Complete	Linear tissue within cyst cavity extending from wall to wall in all planes	None
Septations	Incomplete	Linear tissue within cyst cavity not extending from wall to wall in all planes	None
Solid or Solid-Appe	earing Component		
Solid component	N/A	Focal wall thickening or solid tissue arising from cyst wall/septation that protrudes into cyst cavity ≥3 mm in height	<ul> <li>Excludes blood products and dermoid cyst contents</li> </ul>

Term	Sub-Term	Definition	Comments
			<ul> <li>May use term solid appearing if no internal vascularity</li> </ul>
Papillary projection	N/A	As above and surrounded by fluid on 3 sides	Number important for risk stratification (<4 vs ≥4)
Vascularity			
Colour score (CS)	N/A	Overall subjective assessment of lesion vascularity categorized numericallyCS 1 = No flowImage: CS 2 = Minimal flowCS 2 = Minimal flowImage: CS 3 = Moderate flowCS 3 = Moderate flowImage: CS 4 = Very strong flow	<ul> <li>Applies to the solid components of a cystic lesions and all solid lesions</li> <li>Does not include flow in surrounding ovarian parenchyma</li> </ul>
Peripheral flow	N/A	Circumferential peripheral flow on color Doppler ultrasound	Typical pattern with corpus luteum and hemorrhagic cyst
General and Extra-	Ovarian Findings		
	Physiologic	Confined to pouch of Douglas and below uterine fundus when anteverted/anteflexed or between uterus and urinary bladder when retroverted/retroflexed	Considered non-pathologic
Peritoneal fluid	Ascites	Fluid extends beyond pouch of Douglas or cul-de-sac and above uterine fundus when anteverted/anteflexed, and anterior/superior to uterus when retroverted/retroflexed	± internal echoes; more suspicious for malignancy if echoes present

Term	Sub-Term	Definition	Comments
Peritoneal nodules	N/A	Nodularity or focal thickening of the peritoneal lining or along the serosal surfaces	Associated with peritoneal carcinomatosis

The sections below describe the risk stratification and management recommendations for ovarianadnexal lesions described using the O-RADS<sup>™</sup> lexicon. The **O-RADS<sup>™</sup> risk stratification and management system** is intended for the average risk person without acute/emergent symptoms or known risk factors for ovarian malignancy.

#### **Classic Benign Lesions**

The following table describes **risk stratification and management for lesions that fit into the "classic benign" category**. It has been reproduced (with slight modifications of management recommendations to reflect the Ontario healthcare context, in accordance with an agreement between Ontario Health and the ACR) from: American College of Radiology Committee on O-RADS<sup>™</sup> (Ovarian and Adnexal). O-RADS<sup>™</sup> US v2022. 2022. American College of Radiology. Available at: https://www.acr.org/-/media/ACR/Files/RADS/O-RADS/US-v2022/O-RADS--US-v2022-Assessment-Categories.pdf<sup>11</sup>

# Table 2. O-RADS<sup>™</sup> Ultrasound Risk Stratification and Management System for Classic Benign Lesions (O-RADS<sup>™</sup> 2)

Lesion	initial or follow-up exam, use other lexicon descriptors (e.g.,		
Typical Hemorrhagic Cyst	<ul> <li>Unilocular cyst, no internal vascularity*, and at least one of the following:</li> <li>Reticular pattern (fine, thin intersecting lines representing fibrin strands)</li> <li>Retractile clot intracystic component with straight, concave, or angular margins)</li> </ul>	<ul> <li>Imaging*:</li> <li>Premenopausal: <ul> <li>≤5 cm: None</li> <li>&gt;5 cm but &lt;10 cm: Follow-up US in 2-3 months</li> </ul> </li> <li>Postmenopausal: <ul> <li>&lt;10 cm, options to confirm include:</li> <li>Follow-up US in 2-3 months</li> <li>US specialist (if available)</li> <li>MRI (with O-RADS MRI score)</li> </ul> </li> <li>Clinical: Referral to a Gynecologist**</li> </ul>	

Lesion	initial or follow-up exam, use other lexicon descriptors (e.g.,	Management If sonographic features are only suggestive, and overall assessment is uncertain, consider follow-up US within 3 months.
		Note: Hemorrhagic cysts typically do not occur in post-menopausal people. If this is the case for your person, consider recategorizing the lesion with other lexicon descriptors.
Typical Dermoid Cyst	<ul> <li>Cystic lesion with ≤3 locules, no internal vascularity*, and at least one of the following:</li> <li>Hyperechoic component(s) (diffuse or regional) with shadowing</li> <li>Hyperechoic lines and dots</li> <li>Floating echogenic spherical structures</li> </ul>	<ul> <li>Imaging:</li> <li>≤3 cm: May consider follow-up US in 12 months***</li> <li>&gt;3 cm but &lt;10 cm: If not surgically excised, follow-up US in 12 months***</li> <li>Clinical: Referral to a Gynecologist**</li> </ul>
Typical Endometrioma	Cystic lesion with ≤3 locules, <b>no internal vascularity</b> *, homogeneous low-level/ ground glass echoes, and smooth inner walls/ septation(s) • ± Peripheral punctate echogenic foci in wall	<ul> <li>Imaging: <ul> <li>Premenopausal: <ul> <li>&lt;10 cm: If not surgically excised, follow-up US in 12 months***</li> </ul> </li> <li>Postmenopausal: <ul> <li>&lt;10 cm and initial exam, options to confirm include:</li> <li>Follow-up US in 2-3 months</li> <li>US specialist (if available)</li> <li>MRI (with O-RADS MRI score)</li> </ul> </li> <li>Then, if not surgically excised, recommend follow-up US in 12 months***</li> </ul></li></ul>

Lesion	initial or follow-up exam, use other lexicon descriptors (e.g.,	Management If sonographic features are only suggestive, , and overall assessment is uncertain, consider follow-up US within 3 months.	
Typical Paraovarian Cyst	Simple cyst separate from the ovary	Imaging: None Clinical: None	
Fluid collection with ovary at margin or suspended within that conforms to adjacent pelvic organsPeritoneal Inclusion Cyst± Septations (representing adhesions)			
Typical Hydrosalpinx	<ul> <li>Anechoic, fluid-filled tubular structure</li> <li>± Incomplete septation(s) (representing adhesions)</li> <li>Endosalpingeal folds (short, round projections around the inner walls)</li> </ul>	Imaging: None Clinical: Referral to a Gynecologist**	

MRI = magnetic resonance imaging; US = ultrasound

\*Excludes vascularity in walls or intervening septation(s)

\*\*As needed for management of clinical issues

\*\*\*There is currently a paucity of evidence for defining the need, optimal duration, or interval of timing for surveillance. If stable, consider US follow-up at 24 months from initial exam, then as clinically indicated. Specifically, evidence does support an increasing risk of malignancy in endometriomas following menopause and those present greater than 10 years. See <u>O-RADS US Risk</u> <u>Stratification and Management System: A Consensus Guideline from the ACR O-RADS Committee</u> for additional information.

+The recommendation differs from O-RADS<sup>™</sup> v2022.

#### **Ovarian-Adnexal Lesions**

The following table describes **risk stratification and management for lesions that do not fit into the "classic benign" category**. It has been reproduced (with slight modifications of management recommendations to reflect the Ontario healthcare context, in accordance with an agreement between Ontario Health and the ACR) from: American College of Radiology Committee on O-RADS<sup>™</sup> (Ovarian and Adnexal). O-RADS<sup>™</sup> US v2022. 2022. American College of Radiology. Available at: <u>https://www.acr.org/-/media/ACR/Files/RADS/O-RADS/US-v2022/O-RADS--US-v2022-Assessment-Categories.pdf</u><sup>11</sup>

Please note:

- If it is unclear which O-RADS<sup>™</sup> score (risk category) a lesion belongs in, choose the higher risk category (e.g., if a lesion could be O-RADS<sup>™</sup> 2 or O-RADS<sup>™</sup> 3, it is reported as O-RADS<sup>™</sup> 3).<sup>9,10</sup>
- Referral to *either* ultrasound specialist or MRI are recommended, but both should not be simultaneously requested.
- For higher risk category lesions, referral for management by a gynecologist or gynecologic oncologist should not be delayed by additional imaging. Both referrals to imaging and care provider can occur concurrently, as needed.

# Table 3. O-RADS<sup>™</sup> Ultrasound Risk Stratification and Management System Adapted for the Ontario Healthcare Context

0-	Risk			Management		
RADS™ Score	Category	Lexicon Descriptors		Premenopausal	Postmenopausal	
0	Incomplete Evaluation [N/A]		nt for risk stratification cannot be d due to technical factors	Repeat US study	or MRI	
	Normal	No ovarian lesion				
1	1 Ovary Physiologic cyst: follicle ( $\leq 3$ cm) $\leq 3$ cm)		e (≤3 cm) or corpus luteum (typically	None		
	Almost certainly benign [<1%]	Simple Cyst	≤3 cm	N/A (see follicle)	None	
			>3 to 5 cm	None	Follow-up US in 12 months*	
			>5 to <10 cm	Follow-up US in 12 months*		
2		certainlyUnilocular, smooth, non-simple cyst, smooth (internal echoes and/or incomplete septations)	non-simple cyst,	≤3 cm	None	Follow-up US in 12 months*
			echoes and/or incomplete	>3 cm to <10 cm	Follow-up US in (	6 months*
		Typical benign ovarian lesion (Table 2)	<10 cm			

		Typical benign extraovarian lesion (Table 2)	Any size	See Table 2 (Classic Benign Lesions) for descriptors and management
		Typical benign ovarian lesion (Table 2), ≥10 cm		
		Uni- or bilocular cyst, s	mooth, ≥10 cm	<ul> <li>Imaging:</li> <li>If not surgically excised,</li> </ul>
	Low Risk	Unilocular cyst, irregula	ar, any size	consider follow-up US within 6
3	Malignancy	Multilocular cvst. smoc	oth. <10 cm. CS <4	<ul> <li>months**</li> <li>If solid, may consider US</li> </ul>
	[1 - <10%]	Solid lesion, ± shadowi	ng, smooth, any size, CS = 1	specialist (if available) or MRI
		Solid lesion, shadowing	g, smooth, any size, CS 2-3	(with O-RADS MRI score)*** Clinical: Referral to a gynecologist
		Bilocular cyst without solid component(s)	Irregular, any size, any CS	Imaging
		Multilocular cyst	Smooth, ≥10 cm, CS <4	<ul><li>Imaging:</li><li>Options include:</li></ul>
	Intermedia	without solid	Smooth, any size, CS = 4	• US specialist (if
	te	component(s)	Irregular, any size, any CS	available) ○ MRI (with O-RADS
4	Risk [10 - <50%]	Unilocular cyst with solid component(s)	<4 pps or solid component(s) not considered a pp, any size	MRI score)***
		Bi- or multilocular cyst with solid	Any size, CS = 1-2	Clinical: Referral to a gynecologist with gyne-oncologist consultation or solely by gyne-oncologist
		Solid lesion, non- shadowing	Smooth, any size, CS = 2-3	or solely by gyne-oncologist
		Unilocular cyst, ≥ 4 pps	, any size, any CS	Imaging: While referral pending,
5	High Risk	Bi- or multilocular cyst with solid component(s), any size,		may consider ordering a staging
	[≥50%]	Solid lesion, ± shadowing, smooth, any size, CS = 4		CT (chest, abdomen, pelvis) <sup>+</sup>
		Solid lesion, irregular, a	any size, any CS	Clinical: Direct urgent referral to a
		Ascites and/or peritoneal nodules****		gyne-oncologist <sup>+</sup>

CS = colour score; gyne = gynecologic; MRI = magnetic resonance imaging; N/A = not applicable; US = ultrasound; pps = papillary projections

\* Shorter imaging follow-up may be considered in some scenarios (e.g., clinical factors). If smaller ( $\geq 10 - 15\%$  decrease in average linear dimension), consider follow-up US at 12 and 24 months from initial exam, then management per gynecology. For changing morphology, reassess using lexicon descriptors. Clinical management with gynecology as needed.

\*\* There is a paucity of evidence for defining the optimal duration or interval for imaging surveillance. Shorter follow-up may be considered in some scenarios (e.g., clinical factors). If stable, follow-up at 12 and 24 months from initial exam, then as clinically indicated. For changing morphology, reassess using lexicon descriptors. \*\*\* MRI with contrast has higher specificity for solid lesions, and cystic lesions with solid component(s).

\*\*\*\* Not due to other malignant or non-malignant etiologies; specifically, must consider other etiologies for ascites in categories 1-2.

+The recommendation differs from O-RADS<sup>™</sup> v2022.

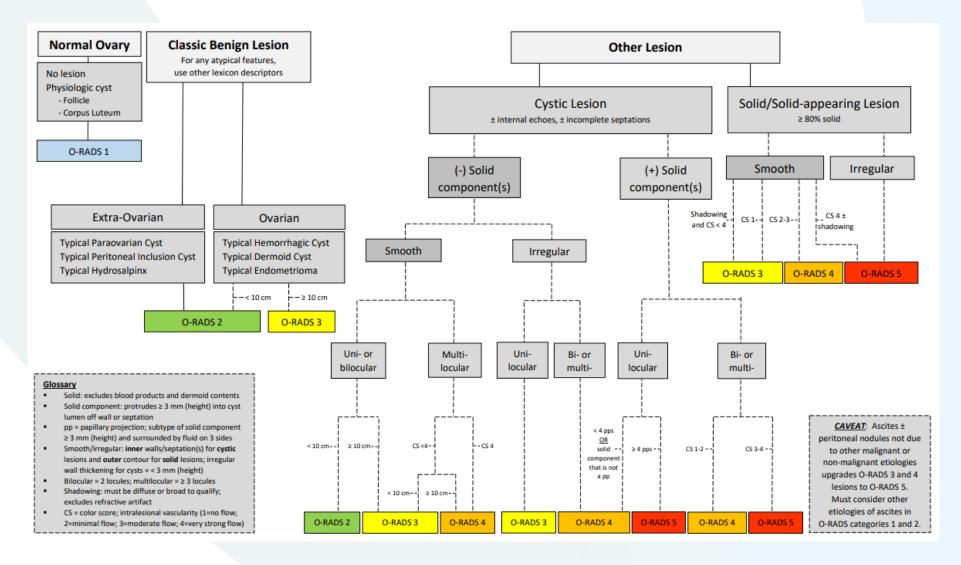


Figure 1. O-RADS™ Ultrasound v2022 Assessment Categories Algorithm

# Tips for Clinical Management of the O-RADS<sup>™</sup> Risk Categories

# When Additional Imaging and/or Re-Assessment may be Needed to Help Characterize an Ovarian-Adnexal Lesion

#### **O-RADS<sup>™</sup> 2, Non-Classic Suspected Benign**

- For suspected, but non-classic hemorrhagic cyst in premenopausal or perimenopausal people, short term follow-up ultrasound may show resolution confirming benign physiologic nature.
- For suspected but non-classic dermoid, MRI may confirm intralesional fat increasing confidence in diagnosis.
- For suspected but non-classic endometrioma, MRI may confirm typical T1 hyperintense blood products with T2 shading.
- For other suspected but non-classic lesions, follow-up ultrasound may ensure stability providing reassurance of benign/indolent nature.

#### **O-RADS<sup>™</sup> 2, Almost Certainly Benign**

- For non-simple unilocular or bilocular cyst, smooth inner margin, 3-10 cm, postmenopausal patient, follow-up ultrasound may provide reassurance by demonstrating stability in these lesions.
- MRI may be useful to confirm absence of solid components or septations in lesions which are larger or difficult to interrogate fully on ultrasound.

#### **O-RADS<sup>™</sup> 3, Low Risk of Malignancy**

- For solid smooth lesions CS=1 suspected to represent fibroma, either follow-up US in 6 months or referral to an ultrasound specialist may improve confidence in diagnosis. Alternatively, MRI may confirm the presence of T2 dark fibrous tissue confirming diagnosis of fibroma.
- If assessment for vascularity is technically challenging on ultrasound, MRI may be helpful to look for enhancement of suspected solid components.
- For multilocular lesions with solid component and shadowing suspected to represent cystadenofibroma, MRI may confirm T2 dark fibrous component.

#### O-RADS<sup>™</sup> 4, Intermediate Risk of Malignancy

- If assessment for vascularity is technically challenging on ultrasound, MRI may be helpful to look for enhancement of suspected solid components.
- Determining the lesion origin on US can be problematic in lesions greater than 10 cm or lesions from other pelvic compartments as they may mimic ovarian pathology. Cross sectional imaging, either by CT or MRI, can help ascertain origin.

#### When an Ultrasound Specialist may be Needed to Help Characterize an Ovarian-Adnexal Lesion

- An ultrasound specialist may be helpful if a classic benign lesion is suspected, but the appearance is non-classic and there is diagnostic uncertainty.
- In the current iteration, the O-RADS<sup>™</sup> 4 category has a broad range. An ultrasound specialist may be helpful to assess an O-RADS<sup>™</sup> 4 lesion and provide expert opinion that allows for further risk stratification within this category. The literature is continuing to evolve in risk management of this category.

# When Additional Imaging and/or Re-Assessment is Not Needed to Help Characterize an Ovarian-Adnexal Lesion

- If the reporting physician is confident of the diagnosis of a non-classic/atypical appearance of a (classic) benign lesion, additional imaging is not required.
- If a reporting physician is confident of a typical appearance of fibroma, additional imaging is not required.
- If a reporting physician is confident the lesion has features of a high-risk lesion (O-RADS<sup>™</sup> 5) a direct referral to gynecologic oncologist is indicated. The consultation with the specialist should not be delayed by repeat or additional imaging. A staging exam can be requested in the interim while awaiting consultation but should not delay referral.

### Sample Ultrasound Worksheet

The following is an example of a comprehensive ultrasound worksheet that can be modified or simplified to fit local preferences, expertise, workflows, and your unique electronic work environments. We recommend that ultrasonographers and radiologists work with a Picture Archiving and Communication System (PACS) administrator to integrate these documents into local workflow.

The O-RADS<sup>TM</sup> ultrasound worksheet can be found as <u>supplementary materials</u>.

O-RADS<sup>TM</sup> lexicon terms used in this worksheet are defined above in <u>Table 1</u> (page 8) and <u>Table 2</u> (page 12).

O-RADS <sup>™</sup> ADNEXAL LESION WORKSHEET			$\Box$ Consent for TVS	Latex Allergy: 🛛 No 🖓 Yes
Patient Name		MRN _1.	Accession	Date
Age LMP _2.		Postmenopausal <u>3.</u>	_(yrs) Indication	
Labs 4.	CA-125	BhCG	□ WBC	
History/Symptoms*	Fever	Nausea	Vomiting	
Acute Pain	Chronic pain	Bloating	Abnormal uter	ine bleeding
Endometriosis	Weight loss	(lbs.)		
Personal/Family History	BRCA 5.	Breast CA	🗆 Ovarian CA (typ	be) _6
□ RSO 7. □ LSO 8.	Hysterectomy	🗆 Lynch	□ Other <u>9</u> .	

- 1. Medical record number
- 2. For premenopausal individuals, fill in date of last menstrual period.
- People are considered postmenopausal if they have been ≥ 1 year without menses. Fill in the number of years since the person reached postmenopausal status (date of last menses + 1 year). If uterus is absent, consider patient is postmenopausal if >50 years old.
- 4. Fill in the most recent result with local units used for the following tests:
  - a. CA-125: cancer antigen 125
  - b. BhCG: beta human chorionic gonadotropin
  - c. WBC: white blood cell count
- 5. Check this box if the person or their first- or second-degree relatives have a known BRCA pathogenic mutation.
- 6. If the person or their first- or second-degree relatives have a history of breast or ovarian cancer, check the corresponding box.
- 7. RSO: check box if right salpingo-oophorectomy previously performed.
- 8. LSO: check box if left salpingo-oophorectomy previously performed.
- 9. Other relevant history, e.g., history of colon or other cancer.

\*With regards to history it would be ideal to provide all the check box information however we realize this is not always available or practical to obtain.

	R/L	Size (cm) TR x AP x Sag		Physiological Finding(s	3)	
Follicle		TRA AF A Jag	🗆 Unilocular	🗆 Anechoic	□ ≤3 cm	
Corpus Luteum			□ Thick-walled cyst	Crenulated inner ma	irgin	
			Peripheral flow	No internal flow		
			Hemorrhagic (see d	escriptors)		
			Classic Benign Features			
Endometrioma				noes		
			🗆 Unilocular 🛛 Mult	ilocular (≤3) 🛛 Avascula	ar 🛛 Smooth inner wall	
Dermoid Cyst 🛛 Hyperechoic component (or entire lesion) w/ shadowir			/ shadowing			
			□ Hyperechoic lines and dots			
			□ ≤3 locules		No internal flow	
			□ Floating echogenic	spherical structures	Fat-fluid level	
Hemorrhagic Cyst			Reticular pattern	Retracting clot (strate)	aight, angular, concave)	
			Peripheral flow	No internal flow		
Paraovarian Cyst			Simple cyst separat	e from ovary		
			□ Moves independen	tly from ovary with trans	ducer pressure (cine)	
Peritoneal			□ Follows contour of	adjacent organs 🛛 🗌	No mass effect	
Inclusion Cyst			Internal septations	🗆 Ovary at margin 🛛	Ovary within	
Hydrosalpinx			🗆 Tubular 🗆 Endosalp	oingeal folds 🗆 Incomplet	e septations 🗆 Anechoic	

Other Lesions (5 Major Categories)							
	Uni-/Bilocular No Solid	Uni-/Bilocular + Solid	Multilocular (≥3) No Solid	Multilocular (≥3) + Solid	Solid (≥80%)		
Right or Left							
Size (cm) TR X AP X SG							
Average Linear Dimension							
Size (largest solid component, cm)							
Colour Score (1-4)*							
Inner Wall*	<ul><li>Smooth</li><li>Irregular</li></ul>		□ Smooth □ Irregular				
PP*		□ 0-3 □ ≥4					
Internal Contents	<ul> <li>Anechoic</li> <li>Internal echoes</li> </ul>	<ul> <li>Anechoic</li> <li>Internal echoes</li> </ul>	□ Anechoic □ Internal echoes	<ul> <li>Anechoic</li> <li>Internal echoes</li> </ul>	<ul><li>☐ Hypoechoic</li><li>☐ Isoechoic</li><li>☐ Hyperechoic</li></ul>		
Acoustic Shadowing		□ No □ Yes		□ No □ Yes	□ No □ Yes		
Septations	□ None □ Incomplete	□ None □ Incomplete	<ul> <li>□ Smooth</li> <li>□ Irregular</li> <li>□ Thick (≥3 mm)</li> <li>□ ≥10</li> </ul>	□ Smooth □ Irregular □ Thick (≥3 mm) □ ≥10			
External Contour (solid)*					□ Smooth □ Not Smooth		
Ascites*	<ul><li>Anechoic</li><li>Particulate</li></ul>	<ul><li>Anechoic</li><li>Particulate</li></ul>	□ Anechoic □ Particulate	□ Anechoic □ Particulate	□ Anechoic □ Particulate		
Peritoneal Nodules	□ No □ Yes	□ No □ Yes	□ No □ Yes	□ No □ Yes	□ No □ Yes		

Comments:							
Date Prior Imaging:							
Prior Imaging: US MRI CT							
<b>Prior Imaging:</b> New Stable Decreased Increased <b>Size (cm)</b> TR X AP X SG:							
MD SECTION							
O-RADS <sup>™</sup> Risk         □ 1         □ 2         □ 3         □ 4         □ 5							
Category							
O-RADS <sup>™</sup> □ Follow-up US Timing (months) □ Consult Gyne Comments:							
Management 🗆 MR							
□ CT GyneOncologist							
Refer US specialist							
*Definitions: PP = papillary projection: solid component which projects into cyst lumen (surrounded by fluid on 3 sides), measures ≥ 3 mm in							
height, may arise from cyst wall or a septations. Irregular inner wall: focal wall thickening <3 mm in height. Colour Score: 1 = no flow; 2 =							
minimal; 3 = moderate; 4 = very strong flow (subjective). External Contour: Not smooth = lobulated or irregular, Ascites: Fluid extends beyond							
pouch of Douglas or cul-de-sac and above uterine fundus when anteverted/anteflexed, and anterior/superior to uterus when retroverted/retroflexed.							

## Radiologist Reporting Guidance and Sample Reports

This section includes guidance from the ACR on radiologist reporting of ovarian-adnexal lesions and several case examples, with minor changes to better reflect the Ontario healthcare environment in accordance with an agreement between Ontario Health and the ACR.

Please note that this guidance is intended for reporting on ovarian-adnexal lesions specifically and does not include all information required on a full pelvic ultrasound report.

The reporting radiologist will consult the completed ultrasound worksheet before generating the final report, as the worksheet includes most of the required information. Depending on your institution's PACS and Electronic Medical Record (EMR), you may prefer to use a structured report template that includes all the essential components and request that the ultrasonographer enter information directly into a report template rather than using a worksheet as an intermediate step. This can optimize efficiency, reduce transcription errors, and allow the radiologist to focus on correct lesion descriptor choices and the final opinion.

The ACR has also released an application (app) for mobile telephones and tablets to support adnexal mass ultrasound reporting. The app takes an algorithmic approach to risk stratification using the O-RADS<sup>™</sup> lexicon (see Figure 2 in Strachowski L, Jha P, Chawla T, et al.<sup>12</sup>). The algorithm may also be useful for formatting this guidance for electronic reporting systems. The free app can be downloaded by searching "ACR Guidance" in a mobile device's application store (<u>acr.org/-</u>/<u>media/ACR/Files/RADS/O-RADS/ACR-Guidance-App.pdf</u>).

#### O-RADS<sup>™</sup> Ovarian-Adnexal Exam Report – Comments

The following is not intended to represent a complete report template as varying reporting styles and templates are currently employed across practices. The report should include indication, clinical history, findings, and opinion sections, based on the O-RADS<sup>TM</sup> risk stratification for ovarian-adnexal findings.

Note, not all ovarian-adnexal findings warrant an O-RADS<sup>™</sup> assessment. For example, the reporting physician may choose to describe physiological lesions such as follicles or corpora lutea simply as normal. Alternatively, most lesions in the asymptomatic and mildly symptomatic person will be appropriate for the risk categorization/management system. If a person presents with acute/emergent findings, the lexicon remains appropriate, however the risk categorization and management recommendations will not apply. Additionally, if a patient has a pre-existing disease, individualized judgment should be used as to the appropriateness of the risk categorization/management system.

Findings that merit an assessment/management recommendation per the O-RADS<sup>TM</sup> schema include:

1) those that carry some risk of malignancy whether discovered incidentally or during evaluation of a clinical symptom; and

2) those discovered on other imaging modalities for which ultrasound is requested for additional lesion characterization.

#### Indication for Current Exam/Relevant Clinical History:

As menopausal status is relevant (in particular for endometriomas and hemorrhagic cysts), the last menstrual period (LMP, if known), menopausal status or years since menopause should be included as a minimum with the provided clinical information or as a separate entry. If the uterus is absent, consider a person as postmenopausal if >50 years old.

#### Findings:

In general, findings should be clear, and succinct. When describing an ovarian-adnexal finding, the following components are required:

#### a) Location

- i) Situs: right, left, other (i.e., midline, cul-de-sac, etc.)
- ii) Relative to ovary: (intra)ovarian, ovarian/adnexal (if ovarian tissue is not seen), extraovarian or separate from the ovary

#### b) Category/Lesion Type

- i) Physiologic: follicle, corpus luteum
- ii) The term follicle or corpus luteum should be specifically utilized and the term cyst or physiological cyst avoided in order to avoid inadvertent patient worry/concern.
- iii) Classic benign lesion: hemorrhagic cyst, dermoid cyst, endometrioma, paraovarian cyst, peritoneal inclusion cyst and hydrosalpinx
- iv) Lesion: unilocular/bilocular cyst with or without a solid component, multilocular cyst (≥3) with or without a solid component, solid lesion (> 80% solid)

#### c) Descriptors

- i) Follicles and corpora lutea need no additional descriptors if criteria are met. Additional descriptors are optional.
- ii) All classic benign lesions should show no internal vascularity (excluding wall of lesion or intervening septa if present)
- iii) Number of locules should be described (allowed ≤3 for dermoids and endometriomas) and a single locule for a hemorrhagic cyst
- iv) Classic benign lesions should be described using associated descriptors, as in Table 2 (page 12)
- v) For each major category of lesion below, **be sure** to include the following key descriptors to assign O-RADS<sup>™</sup> risk category:

Major Category of Lesion	Key Descriptors for Determining Risk Category
Uni-/Bilocular cyst, no solid component	<ul> <li>No complete septation (partial allowed)</li> <li>Inner wall         <ul> <li>If smooth, include inner contents and size</li> </ul> </li> </ul>
Uni-/Bilocular cyst with solid component	<ul> <li>Number of papillary projections</li> <li>May report as 1, 2, 3 or ≥4</li> <li>For unilocular cysts with solid components, the number of papillary projections may change the risk stratification of the lesion</li> </ul>
Multilocular cyst (≥3), no solid component	<ul> <li>One or more septations</li> <li>&gt;3 locules</li> <li>Extend from wall-to-wall         <ul> <li>Inner wall and septations (smooth or irregular)</li> </ul> </li> </ul>
Multilocular cyst (≥3), with solid component	Colour score
Solid	<ul> <li>Outer contour (smooth or irregular)</li> <li>If smooth, include colour score</li> </ul>

vi) Colour flow may be described using the colour score numeric value (1-4) with associated terminology or terminology alone. The numeric value may be used alone if a legend is included within the report.

Colour score 1 = No flow Colour score 2 = Minimal flow Colour score 3 = Moderate flow Colour score 4 = Very strong flow

vii) If desired, a more extensive list of descriptors included in the full lexicon is available for use and may be accessed at: <u>doi.org/10.1016/j.jacr.2018.07.004</u>

#### d) Size

- i) Maximum diameter is required.
- ii) 3 orthogonal diameters are strongly recommended.

#### Opinion:

#### a) O-RADS<sup>™</sup> Risk of Malignancy Assessment Category

 i) The O-RADS<sup>™</sup> risk of malignancy assessment category should be provided in the opinion section of a report. If there are multiple lesions each will receive a separate O-RADS<sup>™</sup> risk of malignancy category. The O-RADS<sup>™</sup> risk of malignancy assessment category includes the numeric value (0-5) and the risk category (i.e., the associated terminology: "normal ovary," "almost certainly benign," "low risk of malignancy," "intermediate risk of malignancy," "high risk of malignancy"). It is recommended not to include the percent likelihood of malignancy as some risk categories have a broad range and has been perceived as a source of concern to patients who may read their reports prior to seeing their physician.

- ii) The Ovarian-Adnexal Mass Standardized Ultrasound Reporting Working Group recommends following the management guidelines, based on radiologist clinical discretion. We recognize that ordering additional imaging studies may delay patient care, for those with high risk of malignancy, that imaging and appropriate clinical referral occur concurrently. Please see the Tips for Clinical Management section on page 19 for examples of when additional imaging may be indicated.
- iii) Please note that an exam may be considered "O-RADS<sup>™</sup> 0: technically inadequate" when ovarian visualization is expected based on the indication for the exam but is not seen.
- iv) If O-RADS<sup>™</sup> category is indeterminate, ACR guidance suggests that radiologists use the O-RADS<sup>™</sup> management recommendations table (Table 3, page 15) to verify whether different descriptors of the indeterminate features would change the O-RADS<sup>™</sup> assessment category and management strategy. Reporting the highest appropriate O-RADS<sup>™</sup> category is generally preferred. If the O-RADS<sup>™</sup> category is unclear, this may be an appropriate setting where consideration of referral to a colleague with dedicated expertise in ultrasound may be of value.
- b) In general, the opinion should include a brief summary of each lesion with the corresponding O-RADS<sup>™</sup> risk of malignancy assessment category and management recommendation and should be listed from most to least concerning.
- c) In addition to the O-RADS<sup>™</sup> risk of malignancy assessment category, the reporting radiologist should provide their overall clinical opinion regarding most likely diagnosis(es) and patient management, including additional imaging if it is indicated. If a specific pathological diagnosis is favoured, the reporting radiologist may include it in the overall opinion as an adjunct or modifier to the O-RADS<sup>™</sup> risk category.

O-RADS<sup>™</sup> 0 = Incomplete due to technical factors

**O-RADS<sup>™</sup> 1 = Normal/physiologic ovary** 

O-RADS<sup>™</sup> 2 = Almost certainly benign

**O-RADS<sup>™</sup> 3 = Low risk of malignancy** 

**O**-RADS<sup>™</sup> **4** = Intermediate risk of malignancy

#### **O**-RADS<sup>™</sup> 5 = High risk of malignancy

d) Please note that while the radiologist report should include an O-RADS<sup>™</sup> category with corresponding management recommendations, individual management is modifiable based on individual physician judgement.

e) **Optional:** A reference to the original O-RADS<sup>™</sup> risk stratification paper should be included at the end of the report as follows: pubs.rsna.org/doi/10.1148/radiol.2019191150. An updated version, v2022, is available at: acr.org/Clinical-Resources/Reporting-and-Data-Systems/O-RADS.

#### O-RADS<sup>™</sup> Sample Ultrasound Cases and Accompanying Reports for the Ontario Healthcare Context

The following are examples of wording that may be used within the "Findings" and "Opinion" sections of a pelvic ultrasound exam report utilizing O-RADS<sup>™</sup> in Ontario. Risk categorization and management recommendations are based on Table 3 (page 15).

For some cases, we have included 2 sample reports, accounting for nuances in reporting styles.

#### CASE 1: 32-YEAR-OLD, PREMENOPAUSAL, ABNORMAL UTERINE BLEEDING

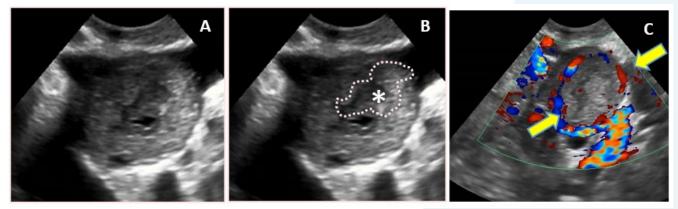


Figure 2. Ultrasound of right ovary. A. Gray scale. B. Same image as A. Dashed outline of renulated inner margin. Internal echoes present (asterisk). C. Demonstrates intense peripheral ring of fire (arrows).

#### Sample Report

**Findings:** Within the right ovary, there is a 2.2 cm thick-walled cystic lesion with internal echoes and intense peripheral vascularity consistent with a corpus luteum.

**Opinion:** Right ovarian 2.5 cm corpus luteum, normal ovary. O-RADS<sup>™</sup> 1. No additional or follow-up imaging is needed.

O-RADS<sup>™</sup> 0 = Incomplete due to technical factors O-RADS<sup>™</sup> 1 = Normal/physiologic ovary O-RADS<sup>™</sup> 2 = Almost certainly benign O-RADS<sup>™</sup> 3 = Low risk O-RADS<sup>™</sup> 4 = Intermediate risk O-RADS<sup>™</sup> 5 = High risk Reference: pubs.rsna.org/doi/10.1148/radiol.2019191150

#### **Tips for Reporting:**

 Including the terms "normal" or "physiological" is encouraged as clinicians may be unfamiliar with O-RADS<sup>™</sup>. It is recommended to avoid the use of the term "cyst" as this may suggest pathology to the referring clinician or patient, thus the choice of the specific term "corpus luteum" is encouraged. The same concept would apply to a follicle (simple cyst ≤3 cm in premenopausal person) in that the more specific term "follicle" should be used rather than the term cyst. Note the phrase "peripheral vascularity" replaces the term "ring of fire".

• The term "complex cyst" should never be used as it is not within the lexicon, is ambigous and nondescriptive.

#### COMPANION CASE: 29-YEAR-OLD, RIGHT LOWER QUADRANT PAIN

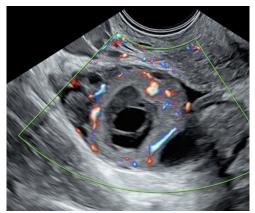


Figure 3. Ultrasound right ovary.

#### Sample Report

Findings: Within the right ovary is a 2.5 cm corpus luteum, normal finding.

**Opinion:** Normal right ovary, O-RADS<sup>™</sup> 1. No additional or follow-up imaging is needed.

O-RADS<sup>™</sup> 0 = Incomplete due to technical factors O-RADS<sup>™</sup> 1 = Normal/physiologic ovary O-RADS<sup>™</sup> 2 = Almost certainly benign O-RADS<sup>™</sup> 3 = Low risk O-RADS<sup>™</sup> 4 = Intermediate risk O-RADS<sup>™</sup> 5 = High risk Reference: pubs.rsna.org/doi/10.1148/radiol.2019191150

**Tips for Reporting:** Brevity in report is appropriate if one is confident in findings. The corpus luteum is a normal finding and thus the opinion may state "normal" O-RADS<sup>™</sup> 1.

#### CASE 2: 64-YEAR-OLD, POSTMENOPAUSAL, BLOATING

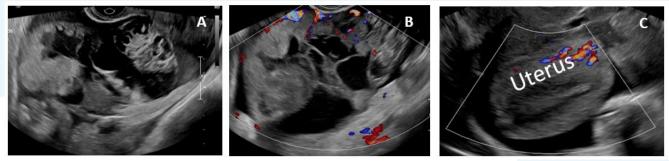


Figure 4. Ultrasound right ovary and uterus. A. Sagittal gray scale ultrasound right ovary which demonstrates a multilocular cyst with solid components. B. Sagittal colour Doppler ultrasound right ovary demonstrates minimal internal vascularity. C. Ascites surrounds the uterus extending above the fundus.

#### Sample Report

**Findings:** Right adnexal multilocular mass with solid components which measures 8.8 x 5.3 x 4.4 cm, minimal internal vascularity (CS 2). Non-particulate ascites is present.

**Opinion:** Multilocular cyst with solid components in right adnexa, presumed ovarian, O-RADS<sup>™</sup> 5. Direct urgent referral to a gynecological-oncologist.

O-RADS<sup>™</sup> 0 = Incomplete due to technical factors O-RADS<sup>™</sup> 1 = Normal/physiologic ovary O-RADS<sup>™</sup> 2 = Almost certainly benign O-RADS<sup>™</sup> 3 = Low risk O-RADS<sup>™</sup> 4 = Intermediate risk O-RADS<sup>™</sup> 5 = High risk Reference: pubs.rsna.org/doi/10.1148/radiol.2019191150

#### **Tips for Reporting:**

- At a minimum, it is required to report the maximum diameter of a lesion. It is however recommended to report all 3 orthogonal measurements. In follow-up, size will be compared to the average linear dimension of the 3 planes (TR, AP, Sag). Orthogonal cine loops are preferred where possible to improve immediate reporting, as well as follow-up comparisons of lesions.
- Ascites is defined as extending above the uterine fundus (anteverted) beyond the pouch of Douglas or cul-de-sac when anteverted/anteflexed or anterior/superior to the retroverted/retroflexed uterus. The presence of ascites will upgrade a mass to O-RADS<sup>™</sup> 5. As per the O-RADS<sup>™</sup> risk stratification chart below, although the lesion size does not change the risk category for a multilocular cyst with solid components, the colour score can potentially upgrade the risk category. A multilocular cyst with solid components with a colour score of 1-2 (no flow to minimal) is considered O-RADS<sup>™</sup> 4 whereas a colour score of 3-4 will upgrade the lesion to O-RADS<sup>™</sup> 5. The presence of ascites, irrespective of colour score, will upgrade the lesion to O-RADS<sup>™</sup> 5, as in this case.

### CASE 3: 38-YEAR-OLD, METASTATIC COLON CANCER PRESENTING WITH PERSISTENT PELVIC PAIN AND DISCOMFORT

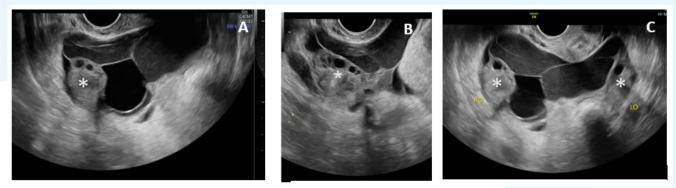


Figure 5. Ultrasound of right adnexa. A. Sagittal US gray scale right adnexa demonstrates a multilocular cyst. The asterisk (\*) denotes the right ovary. B. Transverse US gray scale right adnexa demonstrates a multilocular cyst. The asterisk (\*) denotes the right ovary. C. Transverse US gray scale image of the pelvis with a multiloculated cyst between the ovaries as denoted by the asterisk (\*, \*).

If the reader is not confident in the diagnosis, use descriptor terms and higher O-RADS<sup>™</sup> risk of malignancy score to ensure best practice follow-up.

#### Sample Report 1

**Findings:** Multiloculated cyst without solid components, avascular, midline of pelvis with the ovaries located peripherally and which appears to be conforming to the margins of the pelvis without mass effect. The lesion measures  $10 \times 6.1 \times 3.5$  cm.

**Opinion:** Peritoneal inclusion cyst, O-RADS<sup>™</sup> 2. No further imaging required.

O-RADS<sup>™</sup> 0 = Incomplete due to technical factors O-RADS<sup>™</sup> 1 = Normal/physiologic ovary O-RADS<sup>™</sup> 2 = Almost certainly benign O-RADS<sup>™</sup> 3 = Low risk O-RADS<sup>™</sup> 4 = Intermediate risk O-RADS<sup>™</sup> 5 = High risk Reference: pubs.rsna.org/doi/10.1148/radiol.2019191150

#### Sample Report 2

**Findings:** Multiloculated cyst without solid components, avascular (CS = 1), smooth inner wall, located between the two ovaries. The lesion measures  $10 \times 6.1 \times 3.5$  cm.

**Opinion:** Multilocular cyst without solid component, O-RADS<sup>™</sup> 4. Referral to a gynecologist with gynecologic-oncologist consultation or solely by gynecologic-oncologist. US specialist or MRI may be helpful.

Follow up MRI in the same patient for further characterization confirms the diagnosis of peritoneal inclusion cyst.

#### MRI of pelvis in the same patient:

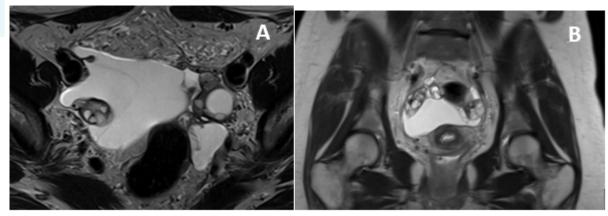


Figure 6. A. TW2, Axial. B. TW2, Coronal.

#### **Tips for Reporting:**

- The sample 1 and 2 reports provide insight into the impact of experience and how nuance may impact differing risks of malignancy. The diagnosis of peritoneal inclusion cyst may be difficult or atypical on ultrasound. This case is somewhat atypical as the multiple locules demonstrated varying echogenicity on ultrasound. In such cases, an MRI can be requested for further characterization.
- The MRI nicely demonstrates the typical pattern of a peritoneal inclusion cyst, a benign lesion belonging to O-RADS<sup>™</sup> 2 classic benign lesion category of extra-ovarian lesions in which size does not affect management.
- Peritoneal inclusion cyst almost always has a history of prior pelvic surgery or inflammation.

#### CASE 4: 18-YEAR-OLD, LEFT PELVIC DISCOMFORT

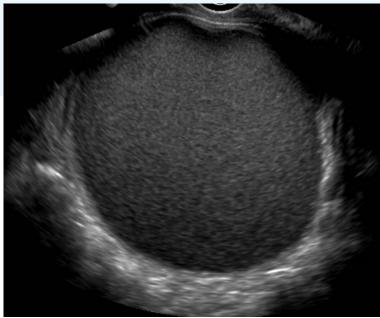


Figure 7. Gray scale ultrasound transvaginal left ovary demonstrates unilocular cyst with homogenous low-level echoes.

Use descriptors to achieve malignancy risk score via O-RADS<sup>™</sup>.

#### Sample Report 1

**Findings:** Left adnexal unilocular cyst, avascular, homogenous low-level echoes, measuring 10.6 x 10.4 x 8.7 cm.

**Opinion:** Unilocular cyst, >10 cm, O-RADS<sup>™</sup> 3. Referral to a gynecologist. Consider follow-up US within 6 months if not surgically excised.

O-RADS<sup>™</sup> 0 = Incomplete due to technical factors O-RADS<sup>™</sup> 1 = Normal/physiologic ovary O-RADS<sup>™</sup> 2 = Almost certainly benign O-RADS<sup>™</sup> 3 = Low risk O-RADS<sup>™</sup> 4 = Intermediate risk O-RADS<sup>™</sup> 5 = High risk Reference: pubs.rsna.org/doi/10.1148/radiol.2019191150

Use when confident in imaging appearance.

#### Sample Report 2

**Findings:** Left adnexal unilocular cyst, avascular, homogenous low-level echoes, measuring 10.6 x 10.4 x 8.7 cm.

**Opinion:** The appearance is consistent with benign classic lesion endometrioma, however as size >10 cm, it is upgraded to O-RADS<sup>™</sup> 3, management by gynecologist is recommended. If the person is post-menopausal, short-term follow-up within 6 months is advised, if not surgically resected. There is a slight increased risk of malignancy in post-menopausal people with lesions that have been present for >10 years.

#### CASE 5: 50-YEAR-OLD, PERIMENOPAUSAL, ELEVATED CA-125

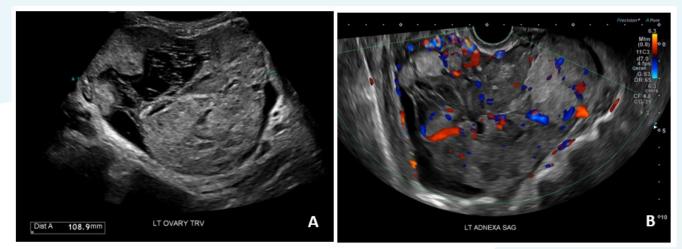


Figure 8. Ultrasound of left adnexa. A. Transverse gray scale left adnexal multilocular solid mass. B. Sagittal colour Doppler US demonstrates moderate vascularity, colour score 3.

#### Sample Report

**Findings:** Left adnexal multilocular cyst with solid components with maximum dimension 10.9 cm, moderately vascular with a colour score of 3. No ascites or peritoneal nodules noted.

**Opinion:** Multilocular cyst with solid components, O-RADS<sup>™</sup> 5. Direct urgent referral to a gynecologic oncologist.

O-RADS<sup>™</sup> 0 = Incomplete due to technical factors O-RADS<sup>™</sup> 1 = Normal/physiologic ovary O-RADS<sup>™</sup> 2 = Almost certainly benign O-RADS<sup>™</sup> 3 = Low risk O-RADS<sup>™</sup> 4 = Intermediate risk O-RADS<sup>™</sup> 5 = High risk Reference: pubs.rsna.org/doi/10.1148/radiol.2019191150

- In the O-RADS<sup>™</sup> 5 category, direct referral to a gynecologic oncologist should be prioritized for best patient outcomes.
- In O-RADS<sup>™</sup> 5 risk category, it is important not to delay specialty oncology care by waiting for interim additional imaging. If additional imaging is required, request for imaging and referral to gynecologic oncology should occur concurrently.
- Solid lesion is defined as > 80% solid; thus, a small number of cystic spaces does not exclude a solid lesion by definition. Nonetheless, note that a bilocular or multilocular cystic-solid lesion with CS 3-4, any size is an O-RADS<sup>™</sup> 5 score.

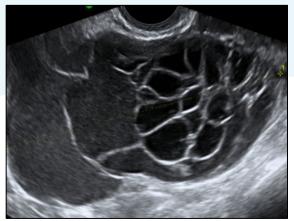


Figure 9. Sagittal gray scale ultrasound of right adnexa.

#### Sample Report

**Findings:** The right ovary is not identified. Within the right adnexa, there is a  $10.5 \times 4.7 \times 8.5$  cm multilocular cyst with no solid component, smooth inner wall, and moderate flow (CS = 3) on colour Doppler imaging.

**Opinion:** Right adnexal 10.5 cm multilocular cyst, O-RADS<sup>™</sup> 4, intermediate risk of malignancy. Patient should be referred for management by a gynecologist with a gynecologic oncologist consultation or solely by a gynecologic oncologist.

This lesion is favored to represent a borderline ovarian tumor in this young patient without solid or vascular component.

O-RADS<sup>™</sup> 0 = Incomplete due to technical factors O-RADS<sup>™</sup> 1 = Normal/physiologic ovary O-RADS<sup>™</sup> 2 = Almost certainly benign O-RADS<sup>™</sup> 3 = Low risk O-RADS<sup>™</sup> 4 = Intermediate risk O-RADS<sup>™</sup> 5 = High risk Reference: pubs.rsna.org/doi/10.1148/radiol.2019191150

- For a multilocular cyst without solid component and smooth inner wall, the risk category is determined by the maximum size of the lesion. Lesions measuring <10 cm fall into the O-RADS<sup>™</sup> 3 Low Risk category whereas those >10 cm are within the O-RADS<sup>™</sup> 4 Intermediate Risk.
- Within the O-RADS<sup>™</sup> 4 category, if the radiologist feels that a lesion is lower risk due to patient factors or specific imaging appearance then this information can be added to the opinion and may help guide appropriate management.

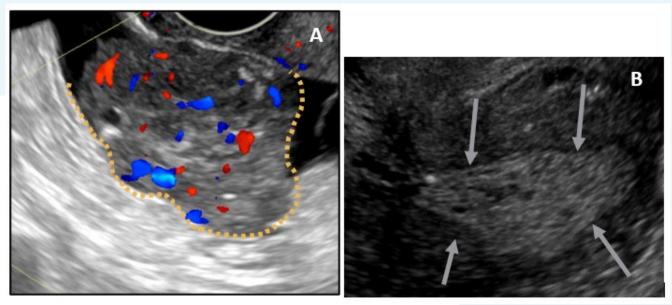


Figure 10. Ultrasound of left adnexa. A. Sagittal gray scale image left adnexa. B. Corresponding image of the endometrium in the same patient shows diffuse thickening and some cystic changes.

# Sample Report 1

**Findings:** In the left adnexa, there is a 4.3 cm solid lesion with lobulated external contour and moderate internal vascularity, colour score 3. No acoustic shadowing. A separate left ovary is not identified. The endometrium is thickened with cystic change. There is a small volume of simple appearing free fluid. No ascites or peritoneal nodules.

**Opinion:** Left adnexal mass, O-RADS<sup>™</sup> 5. Direct urgent referral to a gynecologic oncologist.

O-RADS<sup>™</sup> 0 = Incomplete due to technical factors O-RADS<sup>™</sup> 1 = Normal/physiologic ovary O-RADS<sup>™</sup> 2 = Almost certainly benign O-RADS<sup>™</sup> 3 = Low risk O-RADS<sup>™</sup> 4 = Intermediate risk O-RADS<sup>™</sup> 5 = High risk Reference: pubs.rsna.org/doi/10.1148/radiol.2019191150

# Sample Report 2

**Findings:** The endometrium is thickened with cystic change, measuring 16 mm in the sagittal plane. The uterus is anteverted with no myometrial lesions.

In the left adnexa, there is a 4.3 cm solid lesion with lobulated external contour and moderate internal vascularity, colour score 3. No acoustic shadowing. A separate left ovary is not identified. There is a small volume of simple appearing free fluid. No ascites or peritoneal nodules.

**Opinion:** Left adnexal mass, O-RADS<sup>™</sup> 5 in association with cystic thickened endometrium. The combination of imaging findings is suggestive of a granulosa cell tumor. Direct urgent referral to a gynecologic oncologist.

- In a solid lesion a key feature is to determine risk category is to assess whether the lesion has a smooth or non-smooth (i.e., lobulated, or irregular) external contour. Note: shadowing has also been added as a descriptor for solid lesions. It helps to discriminate lesions of fibromatous origin and improves specificity in lesions with a smooth outer contour. The shadowing should be diffuse or broad.
  - Smooth external contour, colour score 1 (avascular) is O-RADS<sup>™</sup> 3, low risk.
  - Smooth external contour, colour score 2-3 is O-RADS<sup>™</sup> 4, intermediate risk.
  - Non-smooth external contour (i.e., lobulated, or irregular) in a solid lesion irrespective of vascularity or size is considered O-RADS<sup>™</sup> 5, high risk.
- If endometrial thickening was present the combination of lesion appearance with suggestion of endometrial hyperplasia would suggest favored diagnosis of granulosa cell tumor, which pathology confirmed.

#### CASE 8: 28-YEAR-OLD, RIGHT LOWER QUADRANT PAIN

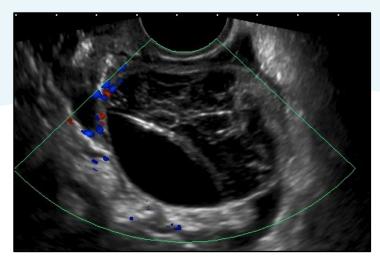


Figure 11. Sagittal ultrasound of right ovary with colour Doppler.

Sample Report (Template Style)

#### Findings:

Laterality: Right Location: Intraovarian Descriptors: Reticular pattern, no internal flow (colour score 1), margin is concave indicating retractile components Maximum size: 4.4 cm

**Opinion:** Right ovarian 4.4 cm hemorrhagic cyst, O-RADS<sup>™</sup> 2. In this premenopausal individual, no additional or follow-up imaging is needed.

O-RADS<sup>™</sup> 0 = Incomplete due to technical factors O-RADS<sup>™</sup> 1 = Normal/physiologic ovary O-RADS<sup>™</sup> 2 = Almost certainly benign O-RADS<sup>™</sup> 3 = Low risk O-RADS<sup>™</sup> 4 = Intermediate risk O-RADS<sup>™</sup> 5 = High risk Reference: pubs.rsna.org/doi/10.1148/radiol.2019191150

- The finding of a hemorrhagic cyst is atypical in post-menopausal person. If present in a perimenopausal person, additional follow-up with ultrasound in 2-3 months is recommended to ensure resolution.
- If the patient is clearly established to be postmenopausal such that there is unlikely to be residual hormonal activity, then referral to a gynecologist or additional imaging for further lesion characterization is recommended.

#### CASE 9: 74-YEAR-OLD, PELVIC DISCOMFORT

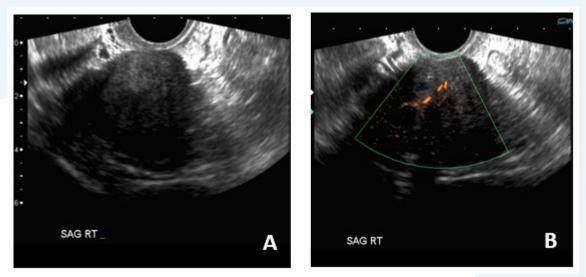


Figure 12. Gray scale and colour doppler images of a transvaginal ultrasound demonstrate the presence of a hypoechoic solid lesion in the right ovary >5 cm in size with acoustic shadowing.

#### Sample Report 1

**Findings:** There is a solid mass in the right ovary measuring 5.6 x 4.2 cm with a smooth contour and minimal flow (CS2). There is no ascites. There is diffuse (broad) acoustic shadowing associated with the lesion.

**Opinion:** Solid right ovarian mass O-RADS<sup>™</sup> 3 intermediate risk category. Referral to a gynecologist. If not surgically excised, follow-up US in 6 months advised.

O-RADS<sup>™</sup> 0 = Incomplete due to technical factors O-RADS<sup>™</sup> 1 = Normal/physiologic ovary O-RADS<sup>™</sup> 2 = Almost certainly benign O-RADS<sup>™</sup> 3 = Low risk O-RADS<sup>™</sup> 4 = Intermediate risk O-RADS<sup>™</sup> 5 = High risk Reference: pubs.rsna.org/doi/10.1148/radiol.2019191150

#### Sample Report 2

**Findings:** There is a 5.6 x 4.2 cm solid lesion in the right ovary in this post-menopausal patient with a smooth outer contour and minimal vascularity (CS2). The lesion demonstrates acoustic shadowing. No ascites.

**Opinion:** The morphology of this lesion is suggestive of a benign lesion in the fibroma/fibrothecoma spectrum, O-RADS<sup>™</sup> 3. MRI correlation is not mandatory but can be obtained for confirmation and reassurance. Referral to a gynecologist. If not surgically excised, follow-up US in 6 months advised.

See MRI image below.

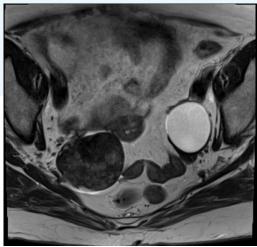


Figure 13. T2W axial image shows T2 hypo-intensity within the previously documented right ovarian lesion entirely characteristic of an ovarian fibroma. (Note: the MRI also demonstrates the left ovary with a simple unilocular cyst (no ultrasound images of the LEFT ovary are provided for the purposes of this case evaluation)).

- Acoustic shadowing is a key predictor of benignity in solid lesions and the current iteration of ORADS<sup>™</sup> reflects this by downgrading smooth solid lesions to ORADS<sup>™</sup> 3 unless the colour score is 4.
- It is useful to capitalize or otherwise accentuate the laterality of a given lesion.

# Common Sources of Error or Ambiguity

Source of Error or Ambiguity	Solution	Тір
Subjective assessment of	In practice, determining	Adjust settings on machine to
colour flow	no/minimal flow is easy as is	optimize sensitivity to ensure
	the presence of strong	that you do not miss minimal
	vascularity (CS4).	flow.
	Discriminating between 2-3 is	
	not likely to impact overall	
	risk category.	
Solid appearing but avascular	The presence of mobile	
mass.	echoes (streaming) is helpful	
	to determine a lesion is cystic	
	rather than solid appearing.	
	Beware of artifactual flow. In	
	minimal flow settings it is	
	important to add spectral	
	Doppler to confirm the	
	presence of internal flow. The	
	absence of flow is less	
	discriminatory.	
Classic benign lesions	Beware of size > 10 cm or	If uncertain or atypical
	atypical features, suspicious	features use lexicon
	features or accelerated	descriptors to assign risk of
	growth.	malignancy score. Specialist
		US referral or MRI may be of
	Newer iteration of O-RADS™	value.
	does include les common	
	features (e.g., echogenic foci	
	in wall of endometriomas).	
Solid component vs papillary	Papillary projection protrudes	
projection	from wall of lesion with an	
	acute angle thus is	
	surrounded by fluid on 3	
	sides and has a height of $\geq 3$	
	mm. A papillary projection is	
External contour of a solid	a type of solid component. Even a small percentage of	
lesion: smooth vs irregular	the cumulative surface	
	contour contributes to this	
	assessment. So, if even a little	
	proportion is irregular or	
	lobulated score in the higher	
	category.	
	cutegory.	

		· · · · · · · · · · · · · · · · · · ·
Internal content of a cystic	Echogenic line/dot	Internal contents of a dermoid
lesion	appearance or echogenic	lesion (fat containing) are not
	floating spherules are not	considered solid components.
	considered solid.	
Low level echoes	Discriminate the uniform low	
	level (ground glass) evenly	
	dispersed echoes seen with	Mar and a second
	an endometrioma with the	
	scattered echoes (unevenly	
	dispersed) of variable size	
	and echogenicity seen with a	
	mucinous lesion. The	
	distinction is not always	Mucinous cystadenoma
	simple.	
		Same Same
		Fra dove otvice vec
		Endometrioma
Utility of spectral Doppler?	No contribution to CS but	
	may help discriminate from	
	artifact when vessels are not	
	clearly seen on CD and to	
	confirm minimal flow.	
Presence of mural calcification	Not a contributor to score. In	
	this circumstance assess the	
	inner wall contour and use	
	that for risk stratification.	

# References

- Froyman W, Timmerman D. Methods of Assessing Ovarian Masses: International Ovarian Tumor Analysis Approach. Obstet Gynecol Clin North Am 2019;46:625-41. <u>doi.org/10.1016/j.ogc.2019.07.003</u>
- Atri M, Alabousi A, Reinhold C, Akin EA, Benson CB, Bhosale PR, et al. ACR Appropriateness Criteria<sup>®</sup> Clinically Suspected Adnexal Mass, No Acute Symptoms. J Am Coll Radiol 2019;16:S77-93. doi.org/10.1016/j.jacr.2019.02.011
- American College of Radiology. American College of Radiology Committee on O-RADS<sup>™</sup> (Ovarian and Adnexal). Virginia USA: American College of Radiology; 2022. Available at: <u>acr.org/Clinical-Resources/Reporting-and-Data-Systems/O-RADS</u>
- 4) American College of Radiology Committee on O-RADS<sup>™</sup> (Ovarian and Adnexal). O-RADSTM ultrasound v2022 lexicon categories, terms, and definitions. American College of Radiology. Available at: <u>acr.org/-/media/ACR/Files/RADS/O-RADS/O-RADS-US-v2022-Lexicon-Termle-2023.pdf</u>
- 5) Andreotti RF, Timmerman D, Benacerraf BR, Bennett GL, Bourne T, Brown DL, et al. Ovarian-Adnexal reporting lexicon for ultrasound: a white paper of the ACR Ovarian-Adnexal reporting and Data System Committee. J Am Coll Radiol. 2018;15:1415–29. <u>doi.org/10.1016/j.jacr.2018.07.004</u>
- 6) American College of Radiology Committee on O-RADS<sup>™</sup> (Ovarian and Adnexal). ACR O-RADS US v2022 updates with rationale. American College of Radiology; 2022. Available at: <u>acr.org/-/media/ACR/Files/RADS/O-RADS/US-v2022/O-RADS-v2022-Updates.pdf</u>
- 7) American College of Radiology. O-RADS for ultrasound: why, what, when and how to use and report. January 14, 2021. Accessed September 13, 2023. Available from: youtube.com/watch?v=6 SVuYPNExs
- 8) American College of Radiology. O-RADS for ultrasound: case examples. September 17, 2021. Accessed September 13, 2023. Available from: <u>youtube.com/watch?v=bzKOoO3-Luc</u>
- American College of Radiology. O-RADS for ultrasound: frequently asked questions. October 21, 2021. Accessed September 13, 2023. Available from: <u>youtube.com/watch?v=41V1Fgc-080</u>
- 10) Andreotti RF, Timmerman D, Strachowski LM, Froyman W, Benacerraf BR, Bennett GL, et al. O-RADS US risk stratification and management system: a consensus guideline from the ACR Ovarian-Adnexal Reporting and Data System Committee. Radiology. 2019;294(1):168–185. <u>doi.org/10.1148/radiol.2019191150</u>
- 11) American College of Radiology Committee on O-RADS™ (Ovarian and Adnexal). O-RADS US v2022.
   2022. American College of Radiology. Available at: <u>acr.org/-/media/ACR/Files/RADS/O-RADS/US-v2022/O-RADS--US-v2022-Assessment-Categories.pdf</u>
- 12) Strachowski LM, Jha P, Chawla TP, Davis KM, Dove CK, Glanc P, et al. O-RADS for ultrasound: a user's guide, From the AJR special series on radiology reporting and data systems. Am J Roentgenol. 2021;216(5):1150–1165. <u>doi.org/10.2214/ajr.20.25064</u>

- 13) Dodge JE, Covens AL, Lacchetti C, Elit LM, Le T, Devries-Aboud M, et al. Management of a suspicious adnexal mass: a clinical practice guideline. Curr Oncol. 2012;19(4):e244-257.
   <u>doi.org/10.3747/co.19.980</u>
- 14) Timmerman D, Valentin L, Bourne TH, Collins WP, Verrelst H, Vergote I. Terms, definitions and measurements to describe the sonographic features of adnexal tumors: a consensus opinion from the International Ovarian Tumor Analysis (IOTA) group. Ultrasound Obstet Gynecol. 2000;16:500– 505. doi.org/10.1046/j.1469-0705.2000.00287.x
- 15) Levine D, Brown DL, Andreotti RF, Benecerraf B, Benson CB, Brewster WR, et al. Management of asymptomatic ovarian and other adnexal cysts imaged at US: Society of Radiologists in ultrasound consensus conference statement. Radiology. 2010;256(3):943–954. doi.org/10.1148/radiol.10100213
- 16) Goldberg-Stein S, Chernyak V. Adding value in radiology reporting. J Am Coll Radiol 2019;16(9 Pt B):1292–1298. doi.org/10.1016/j.jacr.2019.05.042
- 17) Radiological Society of North America. RadReport template library US pelvis [Internet]. Illinois: RSNA [cited 2009 Oct 18]. Available from: radreport.org/home/92/2009-10-18 00:00:00
- 18) Radiological Society of North America. RadReport template library US pelvis [Internet]. Illinois: RSNA [cited 2018 Nov 20]. Available from: radreport.org/home/50531/2018-11-20 19:01:29
- 19) American College of Radiology Committee on O-RADS™ (Ovarian and Adnexal). O-RADSTM pelvic ultrasound exam report essential components and descriptors. American College of Radiology.
   2021. Available at: <u>acr.org/-/media/ACR/Files/RADS/O-RADS/O-RADS\_US-Sample-Reports.pdf</u>
- 20) Anderson TJT, Lu N, Brook OR. Disease-specific report templates for your practice. J Am Coll Radiol. 2017;14(8):1055–1057. <u>doi.org/10.1016/j.jacr.2016.12.019</u>
- 21) Levine D, Patel MD, Suh-Burgmann EJ, Andreotti RF, Benacerraf BR, Benson CB, et al. Simple adnexal cysts: SRU consensus conference update on follow-up and reporting. Radiology. 2019;293(2):359–371. doi.org/10.1148/radiol.2019191354
- 22) Levine D, Brown DL, Andreotti RF, Benacerraf B, Benson CB, Brewster WR, et al. Management of asymptomatic ovarian and other adnexal cysts imaged at US: Society of Radiologists in ultrasound consensus conference statement. Radiology. 2010;256(3):943-954. doi.org/10.1148/radiol.10100213
- 23) Timmerman D, Ameye L, Fischerova D, Epstein E, Melis GB, Guerriero S, et al. Simple ultrasound rules to distinguish between benign and malignant adnexal masses before surgery: prospective validation by IOTA group. BMJ. 2010;341:c6839. <u>doi.org/10.1136/bmj.c6839</u>
- 24) Kaijser J, Sayasneh A, Van Hoorde K, Ghaem-Maghami S, Bourne T, Timmerman D, et al. Presurgical diagnosis of adnexal tumours using mathematical models and scoring systems: a systematic review and meta-analysis. Hum Reprod Update. 2014;20(3):449-462.
   <u>doi.org/10.1093/humupd/dmt059</u>

- 25) Meys MJ, Kaijser J, Kruitwagen RFPM, Slangen BFM, Van Calster B, Aertgeerts B, et al. (2016). Subjective assessment versus ultrasound models to diagnose ovarian cancer: a systematic review and meta-analysis. Eur J Cancer. 2016;58:17-29. <u>doi.org/10.1016/j.ejca.2016.01.007</u>
- 26) Sayasneh A, Kaijser J, Preisler J, Johnson S, Stalder C, Husicka R, et al. A multicenter prospective external validation of the diagnostic performance of IOTA simple descriptors and rules to characterize ovarian masses. Gynecol Oncol. 2013;130(1):140-146. doi.org/10.1016/j.ygyno.2013.04.003
- 27) Sayasneh A, Ferrara L, De Cock B, Saso S, Al-Memar M, Johnson S, et al. Evaluating the risk of ovarian cancer before surgery using the ADNEX model: a multicentre external validation study. Br J Cancer. 2016;115(5):542-548. <u>doi.org/10.1038/bjc.2016.227</u>
- 28) Amor F, Alcázar JL, Vaccaro H, Leon M, Iturra A. GI-RADS reporting system for ultrasound evaluation of adnexal masses in clinical practice: a prospective multicenter study. Ultrasound Obstet Gynecol. 2011;38(4):450–455. <u>doi.org/10.1002/uog.9012</u>
- 29) Meys EMJ, Jeelof LS, Achten NMJ, Slangen BFM, Lambrechts S, Kruitwagen RFPM, et al. Estimating risk of malignancy in adnexal masses: external validation of the ADNEX model and comparison with other frequently used ultrasound methods. Ultrasound Obstet Gynecol. 2017;49(6): 784-792. doi.org/10.1002/uog.17225
- 30) Ulusoy S, Akbayir O, Numanoglu C, Ulusoy N, Odabas E, Gulkilik A. The risk of malignancy index in discrimination of adnexal masses. Int J Gynaecol Obstet. 2007;96(3):186-191. doi.org/10.1016/j.ijgo.2006.10.006
- 31) Akturk E, Karaca RE, Alanbay I, Dede M, Karasahin E, Yenen M, et al. Comparison of four malignancy risk indices in the detection of malignant ovarian masses. J Gynecol Oncol. 2011;22(3):177-182. doi.org/10.3802%2Fjgo.2011.22.3.177
- 32) Campos C, Sarian LO, Jales RM, Hartman C, Araújo KG, Pitta D, et al. Performance of the risk of malignancy index for discriminating malignant tumors in women with adnexal masses. J Ultrasound Med. 2016;35(1):143-152. <u>doi.org/10.7863/ultra.15.01068</u>
- 33) Van Holsbeke C, Van Calster B, Valentin L, Testa Ac, Ferrazzi E, Dimou I, et al. External validation of mathematical models to distinguish between benign and malignant adnexal tumors: a multicenter study by the International Ovarian Tumor Analysis Group. Clin Cancer Res. 2007;13(15 Pt 1):4440-4447. doi.org/10.1158/1078-0432.ccr-06-2958
- 34) National Institute for Health and Care Excellence. Tests in secondary care to identify people at high risk of ovarian cancer. UK: NICE; 2017. 46 p. Available at: <a href="mailto:nice.org.uk/guidance/dg31/resources/tests-in-secondary-care-to-identify-people-at-high-risk-of-ovarian-cancer-pdf-1053745683397">nice.org.uk/guidance/dg31/resources/tests-in-secondary-care-to-identify-people-at-high-risk-of-ovarian-cancer-pdf-1053745683397</a>
- 35) Timmerman D, Van Calster B, Testa A, Guerriero S, Fischerova D, Lissoni A, et al. Ovarian cancer prediction in adnexal masses using ultrasound-based logistic regression models: a temporal and external validation study by the IOTA group. Ultrasound Obstet Gynecol. 2010;36(2):226-234. doi.org/10.1002/uog.7636

- 36) van den Akker PAJ, Aalders AL, Snijders MPLM, Kluivers KB, Samlal RAK, Vollebergh JHA, et al. Evaluation of the risk of malignancy index in daily clinical management of adnexal masses. Gynecol Oncol. 2010;116(3):384-388. <u>doi.org/10.1016/j.ygyno.2009.11.014</u>
- 37) Hakansson F, Høgdall EVS, Nedergaard L, Lundvall L, Engelholm SA, Pedersen AT, et al. Risk of malignancy index used as a diagnostic tool in a tertiary centre for patients with a pelvic mass. Acta Obstet Gynecol Scand. 2012;91(4):496–502. doi.org/10.1111/j.1600-0412.2012.01359.x
- 38) Ameye L, Valentin L, Testa AC, Van Holsbeke C, Domali E, Van Huffel S, et al. A scoring system to differentiate malignant from benign masses in specific ultrasound-based subgroups of adnexal tumors. Ultrasound Obstet Gynecol. 2009;33(1):92-101. <u>doi.org/10.1002/uog.6273</u>
- 39) Van Holsbeke C, Van Calster B, Testa AC, Domali E, Lu C, Van Huffel S, et al. Prospective internal validation of mathematical models to predict malignancy in adnexal masses: results from the international ovarian tumor analysis study. Clin Cancer Res. 2009;15(2):684-691. <u>doi.org/10.1158/1078-0432.ccr-08-0113</u>
- 40) Niemi RJ, Saarelainen SK, Luukkaala TH, Maenpaa JU. Reliability of preoperative evaluation of postmenopausal ovarian tumors. J Ovarian Res. 2017;10(1):15. <u>doi.org/10.1186/s13048-017-0309-4</u>
- 41) Shetty J, Saradha A, Pandey D, Bhat R, Kumar P, Bharatnur S. IOTA simple ultrasound rules for triage of adnexal mass: experience from South India. J Obstet Gynaecol India. 2019;69(4):356-362. doi.org/10.1007/s13224-019-01229-z
- 42) Auekitrungrueng R, Tinnangwattana D, Tantipalakorn C, Charoenratana C, Lerthiranwong T, Wanapirak C, et al. Comparison of the diagnostic accuracy of International Ovarian Tumor Analysis simple rules and the risk of malignancy index to discriminate between benign and malignant adnexal masses. Int J Gynecol Obstet. 2019;146(3):364-369. <u>doi.org/10.1002/ijgo.12891</u>
- 43) Alcazar JL, Pascual MA, Graupera B, Auba M, Errasti T, Olartecoechea B, et al. External validation of IOTA simple descriptors and simple rules for classifying adnexal masses. Ultrasound Obstet Gynecol. 2016;48(3):397-402. <u>doi.org/10.1002/uog.15854</u>
- 44) Hidalgo JJ, Ros F, Aubá M, Errasti T, Olartecoechea B, Ruiz-Zambrana Á, et al. Prospective external validation of IOTA three-step strategy for characterizing and classifying adnexal masses and retrospective assessment of alternative two-step strategy using simple-rules risk. Ultrasound Obstet Gynecol. 2019;53(5):693-700. <u>doi.org/10.1002/uog.20163</u>
- 45) Amor F, Vaccaro H, Alcazar JL, Leon M, Craig JM, Martinez J. Gynecologic imaging reporting and data system: a new proposal for classifying adnexal masses on the basis of sonographic findings. J Ultrasound Med. 2009;28(3):285-291. <u>doi.org/10.7863/jum.2009.28.3.285</u>
- 46) Behnamfar F, Adibi A, Khadra H, Moradi M. Diagnostic accuracy of gynecology imaging reporting and data system in evaluation of adnexal lesions. J Res Med Sci. 2019;24:57. <u>doi.org/10.4103/jrms.jrms\_608\_18</u>

- 47) Diaz L, Zambrano B, Adami FJ, Alcazar JL. External validation of gynecological imaging and reporting data system for sonographic evaluation of adnexal masses. Donanld School of J Ultrasound Obstet Gynecol. 2017;11(2):135-140. <u>dx.doi.org/10.5005/jp-journals-10009-1514</u>
- 48) Froyman W, Wynants L, Landolfo C, Bourne T, Valentin L, Testa A, et al. Validation of the performance of international ovarian tumor analysis (IOTA) methods in the diagnosis of early stage ovarian cancer in a non-screening population. Diagnostics. 2017;7(2):32. doi.org/10.3390/diagnostics7020032
- 49) Cao L, Wei M, Liu Y, Fu J, Zhang H, Pei X, et al. Validation of American College of Radiology ovarianadnexal reporting and data system ultrasound (O-RADS US): analysis of 1054 adnexal masses. Gynecol Oncol. 2021;162(1):107-112. <u>doi.org/10.1016/j.ygyno.2021.04.031</u>

# Appendix A: Methods and Evidence Basis for Endorsement of O-RADS<sup>™</sup>

The appendix containing the methods and evidence supporting the endorsement of O-RADS<sup>™</sup> can be obtained by emailing <u>oh-cco\_cidapinfo@ontariohealth.ca</u>.

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