Alignment of Malpractice Signals to Diagnostic Error:

What's Out There?

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- Disclosure

  Judy Klein has no relevant financial relationships to disclose.

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Alignment of Malpractice Signals to Diagnostic Error: What's Out There?

- Objective
  - Review case scenarios and data for diagnostic error medical professional liability claims and strategies to mitigate risk.

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Diagnostic Error

- Diagnostic Error – definition – National Academy of Medicine/formerly known as Institute Of Medicine
  - Failure to
    - a) establish an accurate and timely explanation of the patient's health problem(s)

    And

    - b) communicate that explanation to the patient.

http://www.nationalacademies.org/hmd/~/media/Files/Report%20Files/2015/Improving-Diagnosis/DiagnosticErrorReportBrief.pdf

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Johns Hopkins Study: $38 Bil Spent on Diagnosis-related Payouts

- Review of 25 years of U.S. malpractice claim payouts
- Diagnostic errors — not surgical mistakes or medication overdoses — accounted for the largest fraction of claims, most severe patient harm, and highest total payouts
- Estimated the number of patients suffering misdiagnosis-related, potentially preventable, significant permanent injury or death in the U.S. ranges from 80,000 to 160,000 annually
- Diagnosis-related payments amounted to **$38.8 billion** between 1986 and 2010

- Source: Johns Hopkins Study Published on April 23, 2013 in BMJ Quality and Safety

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Diagnostic Error – Most Frequent Allegation for Malpractice Cases

- MPL (Medical Professional Liability) Association formerly PIAA (Physicians Insurers Association of America)
- Department of Veterans Affairs
- Kaiser-Permanente Healthcare System
- CRICO-RMF (Harvard)
- NPDB (National Practitioner Data Bank)
- Coverys

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Malpractice Data:
Divining Rod for Patient Safety…

Malpractice Data

- Deeply analyzed cases, particularly valuable if causation factors can be aggregated
- Provides important “signal data” that can guide what to look for in present-day setting
- Has dollars associated with it

Limitations:

- Always a look to the past
- Small numbers raise question of statistical significance
- Unique convergences of factors don’t generally repeat themselves in exactly the same way

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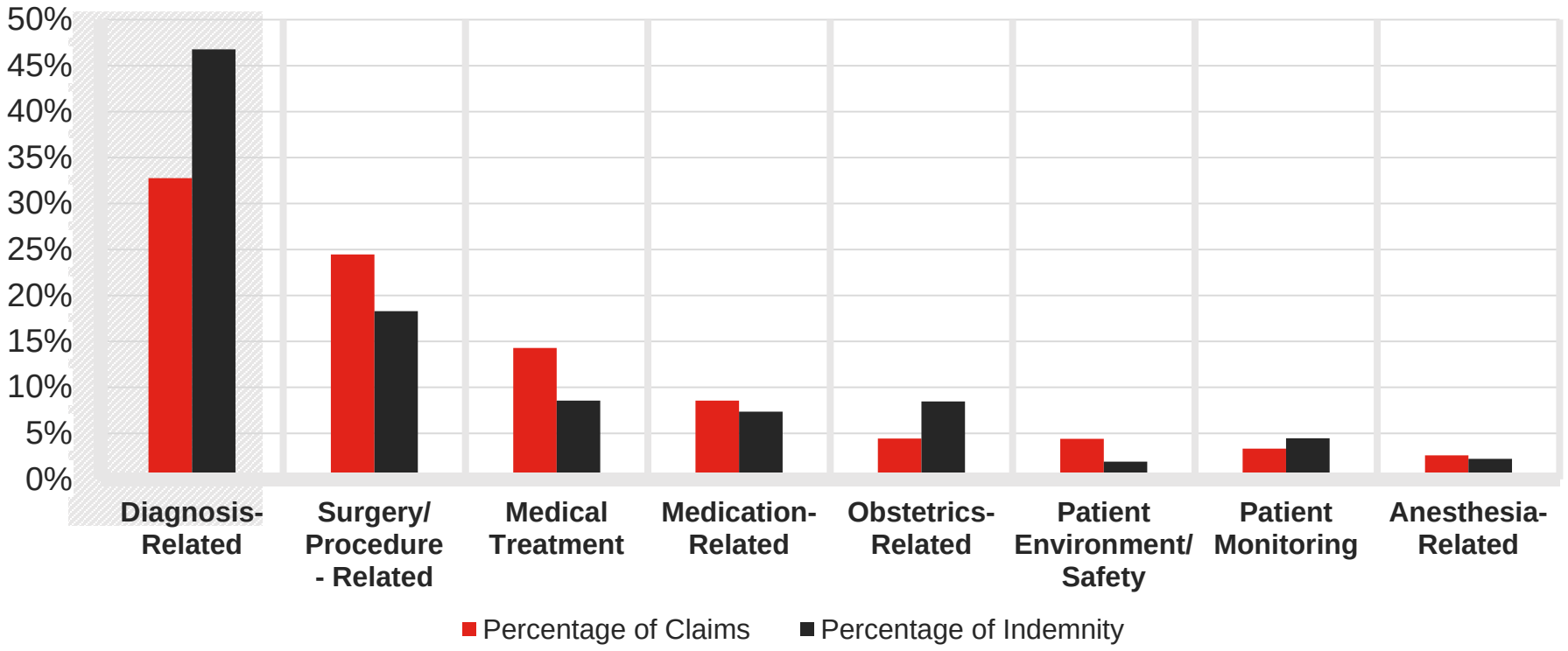
Top Allegation Categories

2013-2017
Diagnosis-Related Closed Claims



Selection: N=10693 closed claims from 2013-2017

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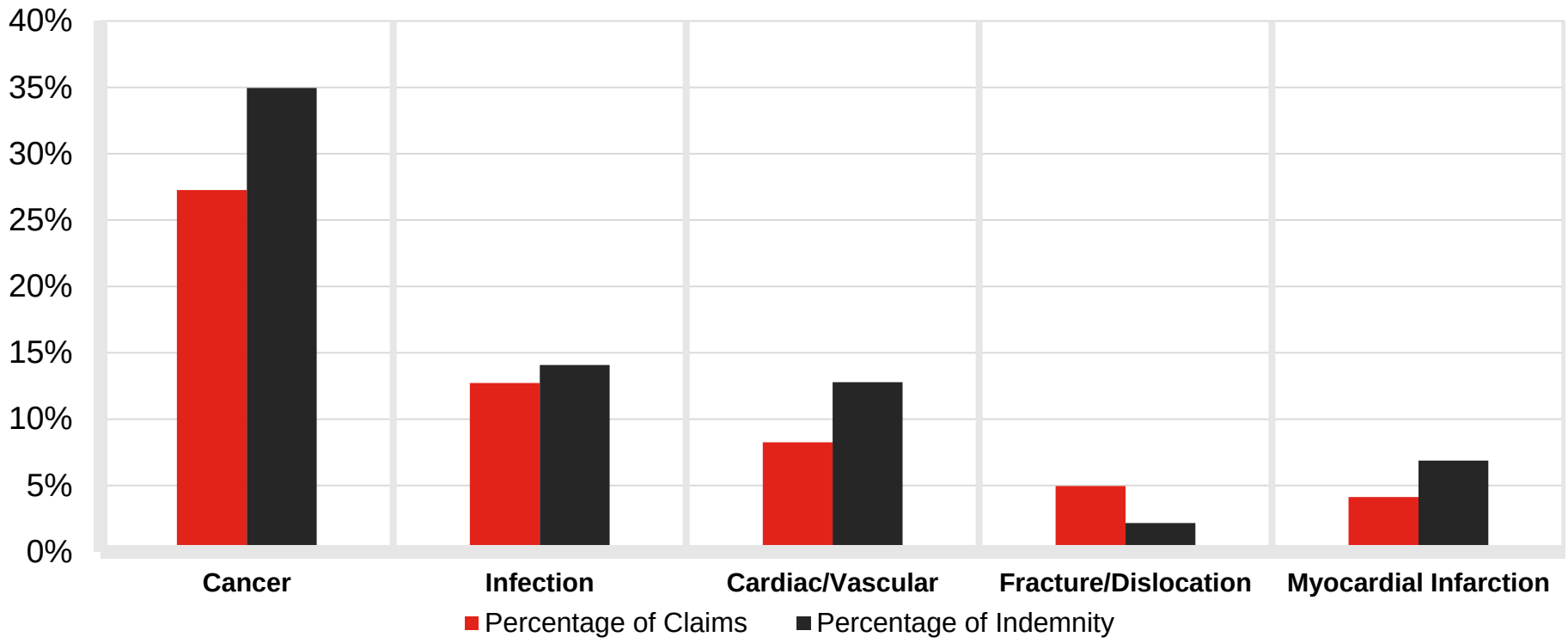
Top Conditions

2013-2017
Diagnosis-Related Closed Claims



Selection: N=3466 closed claims from 2013-2017 with a Diagnosis-Related allegation

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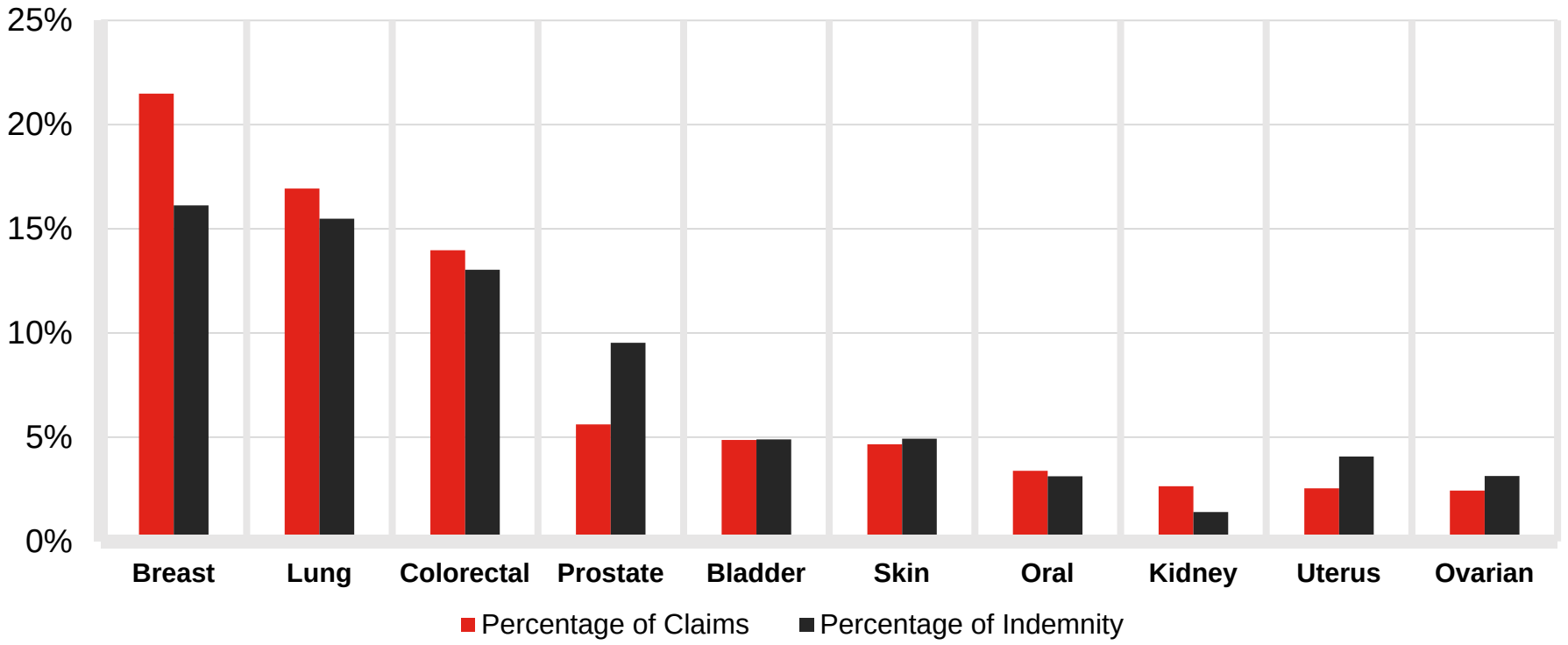
Top Cancers

2013-2017
Diagnosis-Related Closed Claims



Selection: N=945 closed claims from 2013-2017 with a Diagnosis-Related cancer allegation

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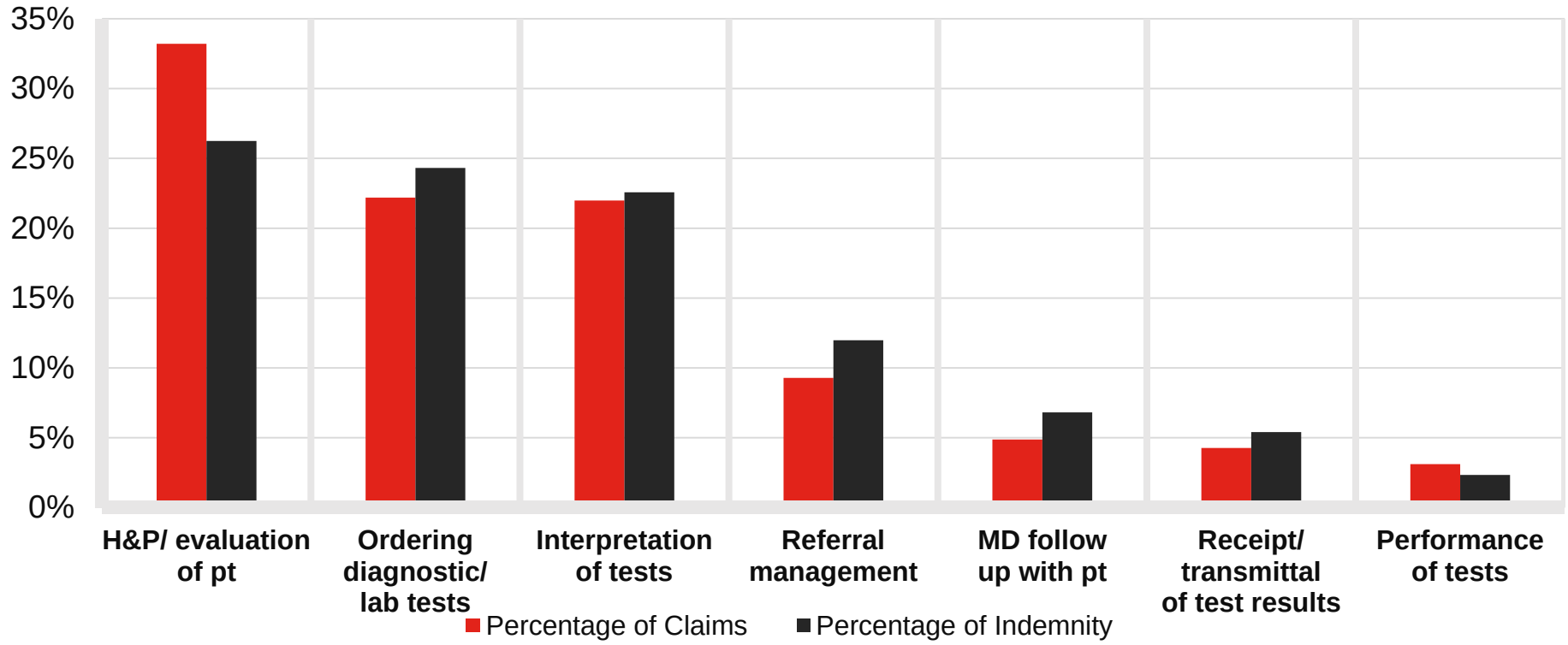
Malpractice Data Signals: Top Allegation Details

2013-2017
Diagnosis-Related Closed Claims



Selection: N=3466 closed claims from 2013-2017 with a Diagnosis-Related allegation

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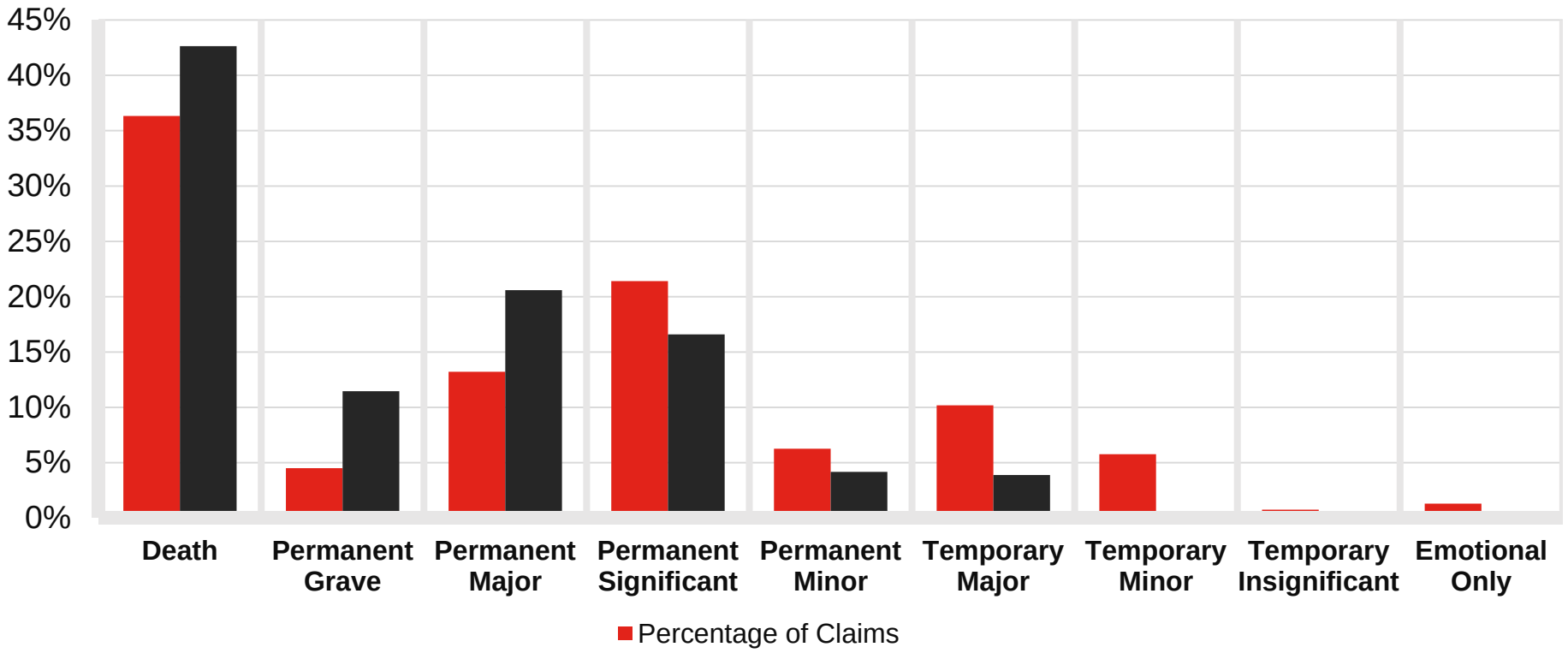
Injury Severity

2013-2017
Diagnosis-Related Closed Claims



Selection: N=3466 closed claims from 2013-2017 with a Diagnosis-Related allegation
Footnote: Injury severity based on National Association of Insurance Commission (NAIC) codes.

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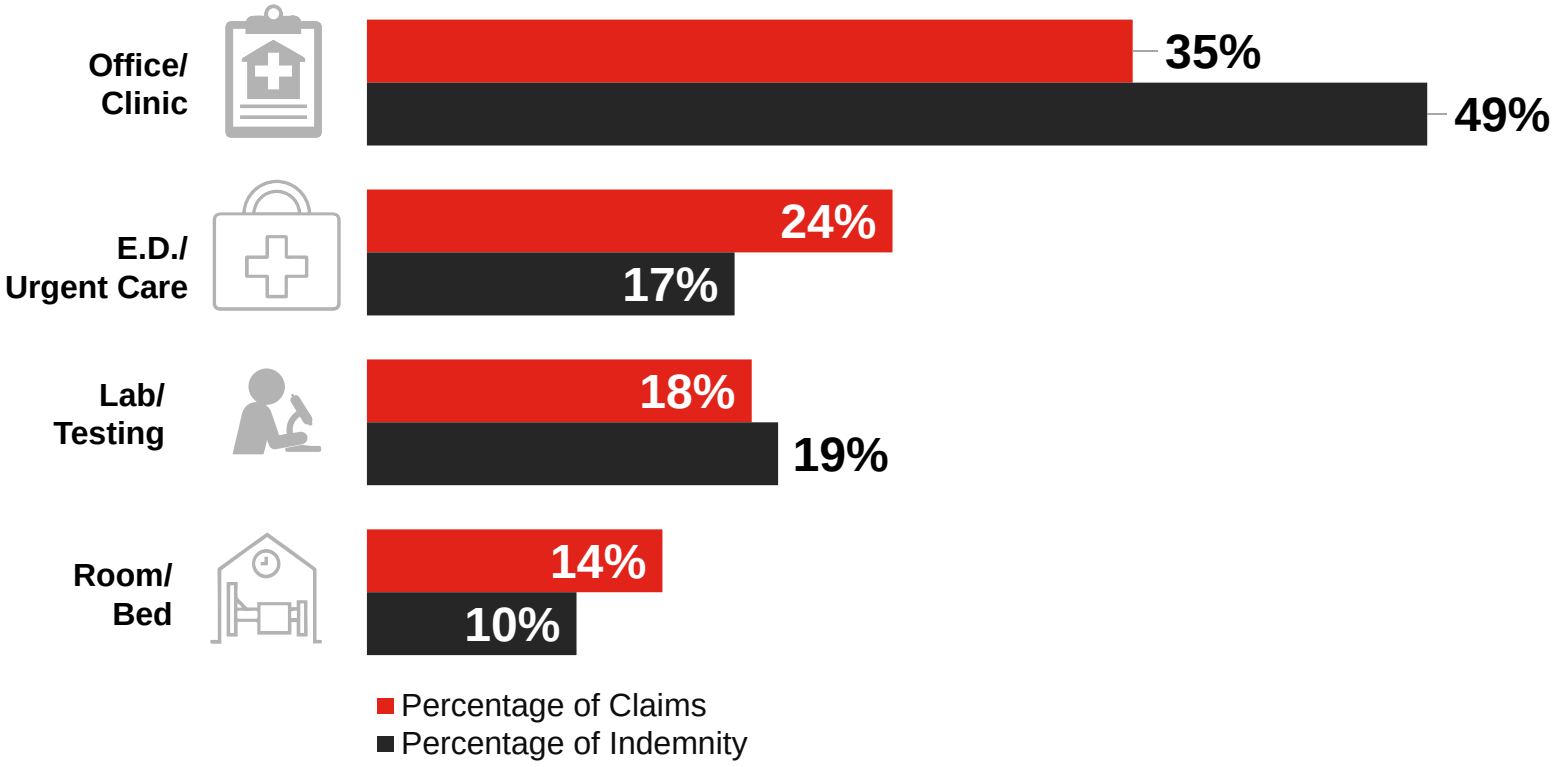
Location

2013-2017
Diagnosis-Related Closed Claims



14 **Selection:** N=3466 closed claims from 2013-2017 with a Diagnosis-Related allegation

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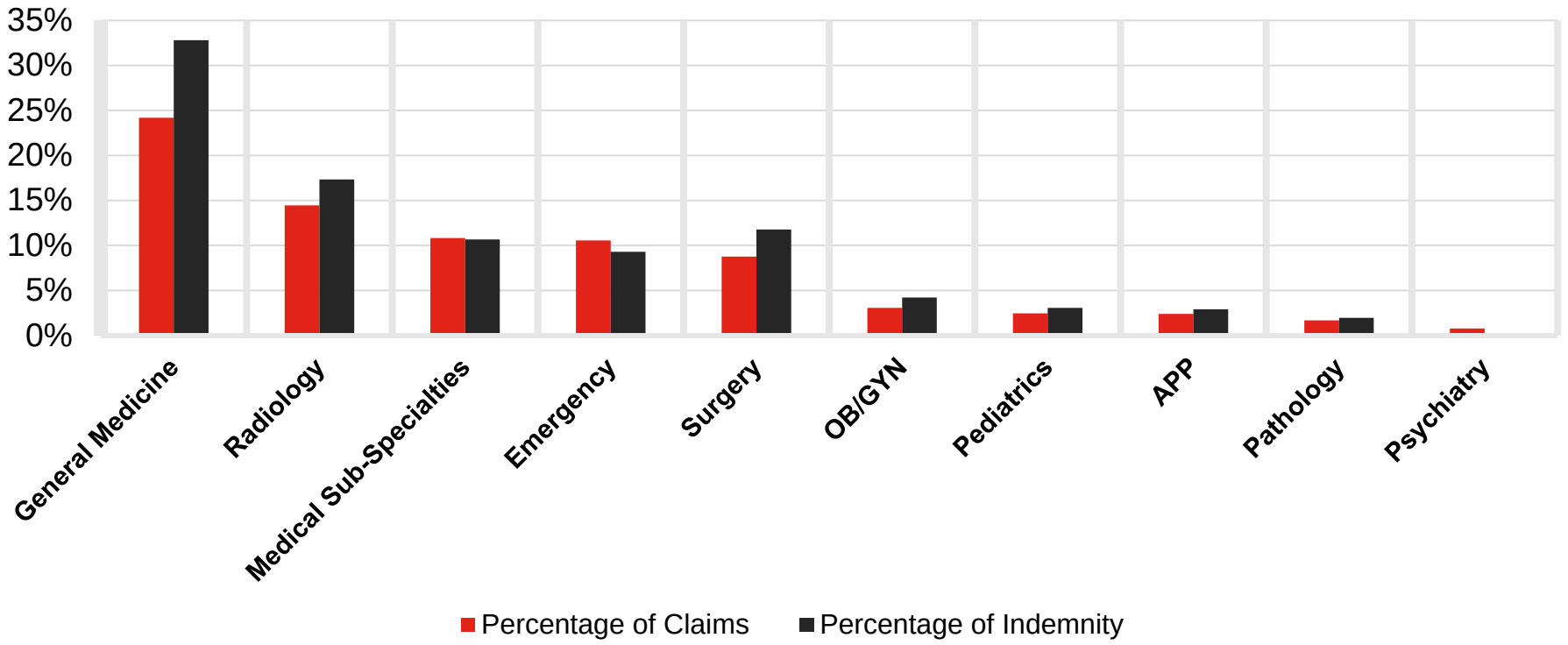
Top Specialties

2013-2017
Diagnosis-Related Closed Claims



Selection: N=3466 closed claims from 2013-2017 with a Diagnosis-Related allegation

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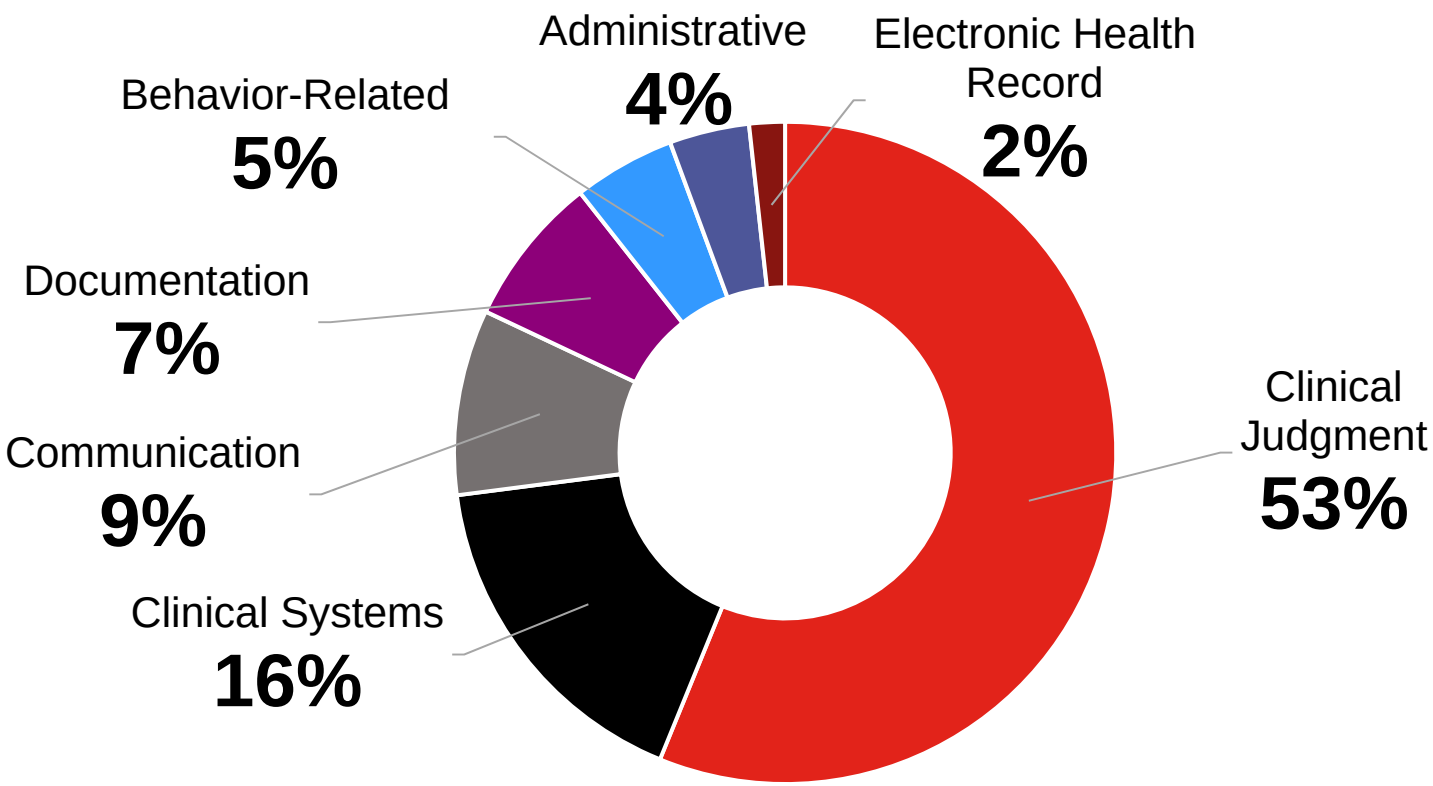
Top Risk Management Categories

2013-2017
Diagnosis-Related Closed Claims



Selection: Closed PL claims from 2013-2017, N=3466 with a Diagnosis-Related allegation an identified Risk Management issue
Footnote: A claim can have more than 1 Risk Management issue.

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Top Risk Management Details – Clinical Judgment

2013-2017
Diagnosis-Related Closed Claims

Clinical Judgment – *Percentage of Claims*

21%	19%	17%	10%	8%
Narrow Diagnostic Focus	Inadequate / Inappropriate Testing	Misinterpretation of Diagnostic Studies	Failure to Adequately Assess Patient's Condition	Failure to Obtain Specialty Consult or Referral

Selection: Closed PL claims from 2013-2017, N=1840 with a Diagnosis-Related allegation and a Clinical Judgment Risk Management issue

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Top Risk Management Details – Clinical Systems

2013-2017
Diagnosis-Related Closed Claims

Clinical Systems – *Percentage of Claims*

17%	16%	13%	10%	8%
Failure to Manage Patient's Follow-up Care	Insufficient Studies (e.g., Imaging)	Results/Specimen Lost, Misfiled, or MD Unaware of Results	Lack of Coordination of Care	Failure to Inform Patient of Test Results

Selection: Closed PL claims from 2013-2017, N=550 with a Diagnosis-Related allegation and a Clinical Systems Risk Management issue

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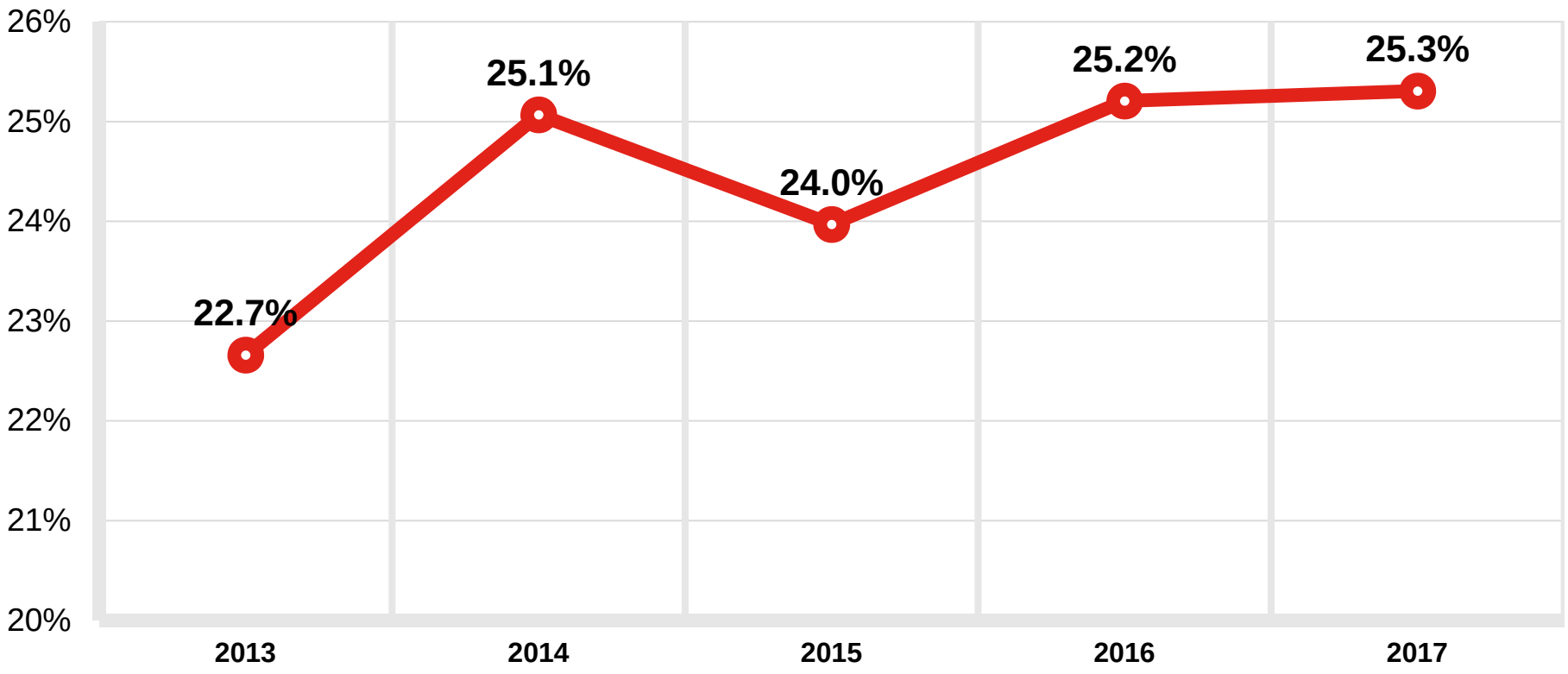
Percentage of Claims Closed with Indemnity Payment

2013-2017
Diagnosis-Related Closed Claims



Selection: N=846 closed claims from 2013-2017 with a Diagnosis-Related allegation and with an indemnity payment

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Diagnostic Error – Case Study
FTD Ovarian CA

- 40 y/o female patient with hx uterine fibroids
  - GYN follows with annual pelvic US
- US showed:
  - 4 cm left ovarian mass:
    - Septated cystic lesion containing an irregularly thickened septum with no obvious associated blood flow
    - Solid portion of the left ovary appeared abnormal
    - Two uterine fibroids were observed
  - MRI recommended for further evaluation of the ovary
- The GYN attempted to contact patient:
  - Phone
  - Letter
  - No response from patient

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Diagnostic Error – Case Study
FTD Ovarian CA

- Patient returns one year later for annual GYN examination
  - Severe lower left abdominal pain
- US obtained/showed:
  - 18 cm (previously 4cm) complex solid left ovarian mass suggestive of neoplasm
  - Bowel Obstruction suggested
- Patient referred to GYN oncologist, taken to OR for exploratory laparotomy
  - Patient aspirated, suffered hypoxic respiratory arrest at time of induction of anesthesia and died
- Autopsy:
    - Dx of ovarian cancer confirmed
    - Large ovarian tumor caused subacute bowel obstruction which, when anesthesia was induced, caused the patient to aspirate and die

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Diagnostic Error – FTD Ovarian CA
Risk Management Issues

- COMMUNICATION
  - MD to Patient:
    - OB/GYN's language/manner of communicating US findings/ need for follow up was insufficient under the circumstances
      - Phone call attempts were not documented
      - Only one letter sent to patient.
        - Tone of the message lacked any sense of urgency
        - Didn't want to frighten patient
  - MD to MD
    - OB/GYN did not attempt to contact the patient's PCP to discuss findings, or see if he was aware of them, or if he could provide assistance in contacting patient

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Diagnostic Error – FTD Ovarian CA
Risk Management Issues

- CLINICAL JUDGMENT
  - Some thought findings on US were reflective of ovarian cancer until proven otherwise
  - OB/GYN left much up to the initiative of the patient
    - Patient needed prompt arrangement for either MRI, a laparoscopic excision of the abnormal ovary, or a referral to a GYN Oncologist for further management
  - Personal and family history considerations
    - Maternal grandmother and 2 maternal cousins with Ovarian CA
    - Patient had personal history of breast cancer at young age
    - Patient not referred from BRCA genetic testing
    - Did order annual CA125

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Diagnostic Error – FTD Ovarian CA
Risk Management Issues

- CLINICAL SYSTEMS
  - US report indicated patient's PCP was to receive a courtesy copy of the report but due to a hospital systems issue, it was not sent.

- OTHER
  - PATIENT ENGAGEMENT
    - Difficult patient to engage
      - No voice mail – never answered calls for 2 months
      - Didn't respond to letter, but returned 1 year later for annual, and experiencing severe abdominal pain
  - ? Insurance Issues
  - ? Anxiety/Avoidance
  - DOCUMENTATION
    - OB/GYN didn't document his phone calls to patient
    - Didn't document patient's claim of insurance issues as cause for her failure to follow up sooner

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Diagnostic Error-
Risk Management Strategies

- Consider using diagnosis-specific clinical decision support resources.
- Implement a formal test tracking and follow-up system that includes standardized procedures, definitions of key terms e.g. critical result, abnormal result
  - Patient name, Test, Date test ordered, Date test report received, Date patient notified of test result and Suggested follow-up
  - Clear guidelines regarding who is responsible for following up on the completion and results of all ordered diagnostic tests and consultations.
- Take advantage of second opinions.
  - If you are unsure about a diagnosis, refer the patient.

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Diagnostic Error-
Risk Management Strategies

- Speak directly with who is providing the results (e.g., radiologists, pathologists).
- Communicate all results, including normal results, to patients and establish time frames for reporting all types of test results.
- Empower patients to serve as safety double-checks.
  - Educate them on which tests are being ordered; why, when and how the results will be communicated; and the importance of following up on tests or recommended treatments.
  - Ensure that patients know how to get back to you if symptoms persist or change.

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Diagnostic Error-
Risk Management Strategies

- Develop policies for addressing patient noncompliance with recommended tests, referrals and treatments.
- Document a patient's refusal to undergo any suggested screening test
- Document all actions pertaining to test ordering, tracking and follow-up.
- Document and update family/personal history e.g. of Cancer on an ongoing basis.

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Diagnostic Error-
Risk Management Strategies

- Establish and adhere to cancer screening guidelines.
  - Encourage screening –explain to patients the importance of cancer screening when appropriate for age
  - Document all Cancer screening tests suggested and performed
  - Send reminders
- Using technology is not a fail-safe method for test tracking and follow-up; have a process for a designated individual to actively check results and follow procedures for responding to tests and following up with patients.
- Monitor processes for test tracking and follow-up on a regular basis and make improvements as necessary.

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Diagnostic Error-
Risk Management Strategies

- Start Talking about Diagnostic Errors/Missteps
  - These aren't always easy to identify
  - Encourage reporting and discussing to learn in non-punitive environment
  - Hold provider-to-provider error discussions under auspices of Risk Management/Quality Improvement Committee.
    - Depending on state peer review protection, practices can achieve protection by participating in a Patient Safety Organization (PSO).

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Diagnostic Error-
Risk Management Strategies

- Use opportunities in your daily work flow to look for diagnostic errors.
    - Include patients in this process. Talk with them when you are not certain about a diagnosis. Advise patient to call if they are not improving or have other symptoms.
- Request follow-up from consulting providers and invite discussion about what could have been done differently.
- Follow-up with other providers when you have questions about the care they provided to your patients. Your approach can be from a personal learning perspective vs. accusatory.

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Where Do Malpractice Signals Lead Us?

Prevention of Diagnostic Errors

- Reliable office-based systems/process that support
  - Thorough documentation
    - Explain thought process
    - Routine updating of clinical history/family history
  - Receipt of test results by ordering providers
  - Tracking/managing follow-up steps related to patient's subsequent care
  - "Close-the-loop" management and accountability of specialty referrals
  - Clarity around results of diagnostic tests and recommended next steps
  - Communication of all test results to patients
- Ongoing, interval-based education of clinicians to avoid fixation, narrow diagnostic focus
- Decision-support tools embedded into the flow of care
- Patient engagement

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Diagnostic Error-Resources

- Institute for Healthcare Improvement/National Patient Safety Foundation
  - https://npsf.site-ym.com/Login.aspx?returl=%2fmembers%2fmy_groups.asp%3f
- National Academy of Medicine
  - https://nam.edu/programs/SocietytoImprove
- Society To Improve Diagnosis in Medicine
  - http://www.improvediagnosis.org/page/Checklist

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Diagnostic Error-Resources

- Agency for Healthcare Research and Quality
  - https://www.ahrq.gov/professionals/education/ahrq-toolkits.html
- IMreasoning
  - http://imreasoning.com
  - Podcast to inspire critical thinking
- The Human Diagnosis Project's Global Morning Report
  - www.humandx.org/gmr/about
  - Cases to be solved on mobile devices