

Capstone for Impact Submission | GY2020

Project Title: Cancellation of ordered gadolinium-based contrast media following 2017-2018 guidance from the US Food and Drug Administration

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Branch: Patients and Populations

Path of Excellence: Medical Humanities

If this project can be continued by another UMMS student, please include your contact information or any other details you would like to share here:

Summary: The purpose of this research was to assess the cancellation of ordered gadolinium-based contrast media (GBCM) following updated 2017-2018 guidance from the U.S. Food and Drug Administration (FDA). **This research was submitted as an abstract to the Society of Abdominal Radiology 2020 Meeting in October 2019. It is currently unpublished, please do not disseminate.**

Methodology: This was an IRB-approved, HIPAA-compliant, patient-safety retrospective review. Data was obtained over a 9-month period (May 2018 – January 2019) following new guidance from the FDA (December 2017 [new GBCM labeling], May 2018 [patient handouts]) regarding gadolinium retention. Included MRIs were initially protocolled with a group II GBCM but subsequently performed without contrast material. Examinations for which GBCM was not indicated (n=196) were excluded. The remaining MRIs were coded and analyzed for 15 potential causes of GBCM cancellation. Descriptive statistics were performed. Process control charts were generated to evaluate trends in cancellation over time.

Results: The frequency of cancellations did not significantly vary during the study period (i.e., only common cause variation detected). Patients initiated 35 of 129 cancellations (27.1% [95% CI: 19.5-34.8%]). Zero (0% [95% CI: 0-2.8%]) were recorded as a patient-stated concern for gadolinium retention. “Renal concerns” was the most common recorded reason indicated GBCM was withheld (N=37; 28.7% [95% CI: 20.9–36.5%]).

Conclusion: Patient-initiated cancellation of ordered GBCM remains low following 2017-2018 FDA guidance about updated GBCM labeling and patient handouts. Fear of nephrogenic systemic fibrosis from group II GBCM remains an uncommon reason group II GBCM is avoided.

Reflection/Impact Statement:

You may use the following questions to guide your reflection:

1. *How did the process of conducting this research confront any limitations of your prior thinking?*
While our focus was on cancellation due to gadolinium deposition, this research also identified patient and provider perception of risk of gadolinium based contrast in renal disease. Prior to doing

background research for the project, I assumed poor renal function was a rigorously proven contraindication to MRI contrast and a risk factor for NSF. My background research revealed the incredibly small and questionable risk of NSF and renal injury due to MRI contrast in those with poor renal function. Despite our institution having made policy changes to reflect this (no GFR spot test required prior to MRI contrast for renal disease patients), patients and providers still perceive, as I had, that MRI contrast poses a risk of NSF or renal injury. This research reinforced that there are many well-established beliefs in medicine that will be proved wrong, or are already proved wrong despite clinical practice continuing unchanged. This research also reinforced the clinical significance of perceived risk, and its potential medical consequences if false.

2. *Who could potentially benefit from this CFI project over different timescales and how?*

This research indicates that patients are not cancelling contrast explicitly due to the new medication guides for gadolinium based contrast, though we cannot be sure whether patients are reading the medication guides. That being said, we are unsure of the risk of gadolinium deposition, so mass cancellation of clinically indicated contrast MRIs at this point would likely have worse clinical outcomes. This research will hopefully help inform delivery of this information so it achieves the balance of informed consent without causing decreased risk tolerance for MRI contrast and cancellation of clinically indicated contrasted studies.

3. *What actions will you take afterwards to continue the momentum of this project, and maximise the likelihood of the identified benefits being achieved?*

We are continuing data collection to cover a greater time period before and after policy implementation to better understand trends in cancellation. This data will hopefully help us understand the potential impacts of the medication guides and identify how patient communication and MRI contrast workflow could be improved.

4. *What advice would you give to another student completing their CFI?*

You will do many amazing, interesting projects during medical school. Do not stress too much about which one becomes your CFI. Make your CFI something that can be completed or far along by the time your Dean's Letter is written. There is some benefit to making your CFI related to your residency specialty as it appears on your Dean's Letter. Your PoE project is also listed, so there is room to highlight two projects!