We study the impact of consumer risk perception on firm innovation. Our analysis exploits a major surge in the perceived radiation risk of diagnostic medical devices, following extensive media coverage of a set of over-radiation accidents in late 2009. Difference-in-differences regressions using data on patents and FDA product clearances show that consumers’ increased perception of radiation risk spurred the development of new technologies that mitigated such risk. These findings, together with additional results regarding demand, suggest that changes in risk perception can be an important driver of innovation and shape the direction of technological progress.
Risk Mitigating Technologies: the Case of Radiation Diagnostic Devices

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Abstract

We study the impact of consumer risk perception on firm innovation. Our analysis exploits a major surge in the perceived radiation risk of diagnostic medical devices, following extensive media coverage of a set of over-radiation accidents in late 2009. Difference-in-differences regressions using data on patents and FDA product clearances show that consumers’ increased perception of radiation risk spurred the development of new technologies that mitigated such risk. These findings, together with additional results regarding demand, suggest that changes in risk perception can be an important driver of innovation and shape the direction of technological progress.
1 Introduction

At least since Schmookler (1966), strategy, innovation, and economics scholars have emphasized the link between market demand, innovation incentives, and technological progress. The broad consensus is that market demand plays a crucial role in selecting among the various possible technological paths opened up by scientific and technological progress (Dosi, 1982; Kline and Rosenberg, 1986; Di Stefano, Gambardella and Verona, 2012).

Empirical research has shown that demand steers technological progress through various mechanisms. These include: market size (Acemoglu and Linn, 2004); heterogeneity in consumer needs (Adner and Levinthal, 2001); geographic variation in consumer tastes (Fabrizio and Thomas, 2012); and feedback from customers and lead users (von Hippel, 1986). Despite this extensive literature, shifts in demand driven by the perceived risk of a product have, thus far, attracted little empirical and theoretical attention. Our paper fills this gap by examining firms’ innovation responses to a significant increase in the perceived safety of their products and by characterizing the nature of these resulting innovations.

Changes in risk perception differ from other demand-pull forces in a number of dimensions. First, risk perception has an ambiguous effect on market demand. On the one hand, the consumption of risky products is likely to drop; on the other hand, the willingness to pay for safety features and lower-risk products may increase. While the net outcome of these counteracting effects determines the impact on overall innovation incentives, the incentive to develop risk-mitigating technologies (henceforth, RMTs) is likely to increase. Specifically, RMTs are technologies that reduce the likelihood of adverse events and the extent of harm. Second, changes in risk perception tend to exhibit externalities that impact the entire product category. As a result, their impact on innovation activities is also likely to be shaped by non-market forces such as regulation, the liability systems, and consumer activism. Finally, RMTs do not fit easily in conventional taxonomies of innovation. RMTs may range from incremental to radical innovations; and may involve both products and processes (Cohen and Klepper, 1996). As we will explain, these unique features of risk perception may generate opposite effects at the extensive and intensive margins of consumption, with important implications for the direction of technological progress, competitive advantage, and market structure.
Our empirical analysis exploits a quasi-exogenous surge in risk perception that affected diagnostic medical devices emitting radiation. In October 2009, a medical center in Los Angeles disclosed that it had administered up to eight times the normal radiation to over 200 patients undergoing CT brain perfusion because of erroneous scanner settings caused by user errors. We document a variety of evidence based on industry accounts, congressional hearings, surveys, and field interviews suggesting that the extensive media coverage of these events increased patients’ and medical providers’ perceived risk of CT and other radiation-emitting technologies. The focus of our analysis is the impact of this over-radiation shock on innovation.

Our empirical analysis proceeds in multiple steps. We begin with an examination of the shock’s impact on firm innovation in terms of patenting as well as new product introductions. For patenting, we leverage the detailed patent classification system to define RMTs; that is, we identify patent subclasses related to technologies aimed at protecting against radiation, controlling the level of patient exposure, and detecting device malfunctions. Our baseline result is based on a difference-in-differences analysis that compares patenting in RMT subclasses (treatment group) to patenting in subclasses related to other features of diagnostic radiology devices (control group) before and after the over-radiation shock. We find that after the shock, relative to control subclasses, patenting in RMT subclasses experienced a large and statistically significant increase of over 100 percent. We show that this surge was not driven by differential patenting trends in treated and control subclasses before the shock and that the finding is robust to a number of different specifications and alternative ways to define treatment subclasses. Importantly, we exploit alternative control subclasses to show that potential within-firm substitution effects (e.g., through reallocation of R&D resources from other research activities to RMTs) is likely to be small. This implies an overall increase in innovation in radiology diagnostic devices.

Using FDA data on pre-market notifications, we show that the over-radiation shock also leads to an increase in new product introductions. In particular, the number of new radiology diagnostic devices emitting ionizing radiation increased significantly after the shock relative to other types of devices. Furthermore, using information extracted from the FDA application summary files, we confirm that the increase is driven by products for which radiation safety features are prominent, and that the effect is economically and statistically more significant for devices emitting higher levels of radiation.
Next, we provide more direct evidence for the economic mechanism at play; i.e., that the over-radiation shock led to a shift in users’ preferences. In particular, we show that demand changed at two different margins. First, we examine how the shock affected technology use (the intensive margin); and we show that the number of services rendered for diagnostic procedures involving high radiation experienced a large and sharp drop after 2010. Second, we examine the pattern of technology upgrade (the extensive margin). We show that relative to equipment emitting lower levels of radiation, the propensity to replace or upgrade CT systems by hospitals and clinics increased significantly a couple of years after the shock. In isolation, each of these patterns may be explained by other demand shifters. However, the joint presence of a decline in usage and an increase in equipment upgrade provides a strong support for the mechanism of an increase in perceived risk.

We further complement our aggregate, quantitative analysis with an in-depth description and characterization of the nature of RMTs. Specifically, we document two types of RMTs. The first type can be thought of as ‘low-hanging fruits’, as their goal is to prevent over-radiation errors or to manage dosage more efficiently without a substantial departure from existing technologies. Many of these new features, including alert and notification systems, are implemented by the CT industry through a series of new standards set by the industry association. The second type of RMT is qualitatively different because it requires substantial departure from the method that dominated the CT industry for the last 30 years. This alternative method involves the adoption of a long-shelved technique to reconstruct image data, which requires a significant sacrifice in speed and other aspects of image quality, at least initially. However, it allows for levels of radiation dose reduction that are not achievable by simply ‘tweaking’ the existing technologies. This re-direction of technological trajectories is consistent with the idea that increased demand for safer machines serves as a selection device (Dosi, 1982).

We conclude our empirical analysis by examining the role of large firms in the increase in RMTs. We show that innovation activities in RMTs are economically substantial for both the largest firms and smaller patentees; and relative to patenting stage, the largest firms play a more prominent role than smaller patentees at the commercialization stage. This is especially true for the type of RMTs that requires substantial R&D investment. These patterns are consistent with the nature of changes in risk perception that tend to affect the entire product category, that dominant players are better equipped
to incorporate these changes into new products, and a well-functioning market for technologies. These results also suggest that the over-radiation risk may have perpetuated the market dominance of large firms, rather than diminishing it.

The paper is organized as follows. Section 2 reviews the literature. Section 3 provides background information on CT and the over-radiation shock. Section 4 describes the data and our empirical approach. Section 5 presents the empirical results linking the shock to innovation measures using patent and FDA data. Section 6 reports results on demand changes in terms of equipment upgrades and their usage. Section 7 focuses on CT scanners and provides a characterization of different types of RMTs, and section 8 discusses the role of large incumbent and smaller players. Section 9 concludes.

2 Related literature

Our paper contributes new empirical evidence about the relationship between liability risk and innovation. The first empirical analysis of this relationship was conducted by Viscusi and Moore (1993). Their analysis is guided by a theoretical framework emphasizing how higher liability risk may have an ambiguous effect on innovation. On the one hand, it may decrease R&D incentives because of higher costs; on the other hand, it may also encourage innovation that increases product safety. Empirically, they examine the link between product liability insurance costs and R&D investments in a sample of large U.S. manufacturing firms in the 1980s. They find a strong positive correlation between liability insurance expenditures and firms’ R&D intensity, suggesting that, on average, product liability promotes rather than discourages innovation. Galasso and Luo (2017) re-examine this issue by studying how tort reforms that decrease physicians’ exposure to medical malpractice liability affect medical-device patenting. Theoretically, they also derive off-setting effects: higher liability exposure chills physicians’ demand for new technologies associated with greater risk but increases demand for technologies that reduce injuries. Their empirical results are consistent with Viscusi and Moore (1993) and support the idea that the positive effect of liability on innovation tends to dominate. While these two studies suggest that liabilities may incentivize the development of risk-mitigating technologies, neither paper directly measures this type of innovation. The first contribution of our paper is to characterize and measure...
risk-mitigating technologies and to provide direct evidence for a change in the direction of innovation.

Another limitation of Viscusi and Moore (1993) and Galasso and Luo (2017) is that they exploit cross-industry or state-level variations that are likely to capture a combination of heterogeneous responses by different markets, firms, and technologies. To provide a deeper understanding of the underlying mechanisms, Galasso and Luo (2018) depart from this intra-industry approach and focus on a particular context: medical implants. Specifically, Galasso and Luo (2018) exploit a major quasi-exogenous increase in liability risk faced by US suppliers of polymers used to manufacture medical implants. The findings of their empirical analysis are in sharp contrast with previous studies and show that the surge in suppliers’ liability risk had a large and negative impact on downstream innovation in medical implants, but it had no significant effect on upstream polymer patenting. These results suggest that liability risk can percolate throughout a vertical chain and have a significant chilling effect on downstream innovation. As Galasso and Luo (2018), our paper focuses on a specific context and provides detailed evidence for a specific but different mechanism—revised beliefs on the riskiness of the technology increases user demand for risk-mitigating technologies.\(^1\)

More broadly, our analysis relates to the vast economics and management literatures on the determinants and directions of technical change. Cohen (2010) and Di Stefano, Gambardella and Verona (2012) provide comprehensive overviews of the academic debates on the sources of innovation. While Schmookler’s seminal work on the primary role of market demand raised a number of important empirical and theoretical concerns, more recent studies have made progress addressing these concerns and providing better-identified evidence for the linkages between market demand and innovation (Sutton; 1998; Acemoglu and Linn, 2004; Finkelstein, 2004). We contribute to this line of research by examining the innovation impact of demand shifts driven by changes in users’ risk perceptions.

Our paper also relates to the literature on product recalls, especially the stream of research that explores the spillover effect on competitors who do not suffer direct costs but may experience reduced demand due to consumers’ revised belief about safety of the entire product category. Early literature provides mixed results (Jarrell and Peltzman; 1985; Hoffer et al., 1988 and Barber and Darrough, 1996).\(^1\)

\(^1\)Theoretical work on liability and producer incentives suggest that manufacturers will respond to the demand for safer products through innovation and product redesigns (Daughety and Reinganum, 1995; Hay and Spier, 2005). Our paper provides empirical evidence of these innovation responses.
Later research focuses more on the mechanisms underlying the presence (or lack thereof) of spillover effect (Borenstein and Zimmerman, 1988; Dranove and Olsen, 1994; Freedman et al., 2012). We add to this literature by studying firms’ innovation responses to malfunction of CT scanners. The only paper we are aware of that study the impacts of product recalls on innovation is Ball et al. (2018), also in the context of medical devices. There are important distinctions between our paper and theirs. First, their main focus is on the direct costs of the recalls, the operational disruption and their competitive effects, while we focus on the increase in demand due to greater concerns over product safety. Second, our paper can distinguish the specific type of innovation addressing safety concerns rather than considering the overall innovation activity in the field.

Finally, our analysis is also related to the literature studying the relationship between legal liabilities and medical practice. Most studies in this literature exploit the variations provided by state tort reforms. Results are mixed suggesting a nuanced relationship between liability risk and the intensity of medical practice, depending on the providers’ incentives (Kessler and McClellan, 1996; Currie and MacLeod, 2008; Frakes, 2013). Our paper contributes to this literature providing evidence linking liability concerns with medical technology development, adoption and usage.

3 Background

Computed tomography (CT) is a medical imaging method that combines multiple X-ray projections taken from different angles to produce detailed cross-sectional images of areas inside the body. Judged by primary care physicians to be one of the most important technical innovations in medicine (Fuchs and Sox, 2001), more than 62 million CT scans were performed in 2006 in the U.S.—a drastic increase compared to about 3 million in 1980 (Brennen and Hall, 2007).

A key advantage of CT over standard X-rays and ultrasound is its superior image quality—high-contrast resolution that detects tissue types differing only slightly in physical densities; elimination of possible obstructions; and the ability to see from different angles and planes. Magnetic resonance imaging (MRI) generates more detailed images of soft tissues and ligaments and is more suitable for examining, for example, the spinal cord and nerves, but it takes 30 minutes to an hour and usually
cannot be used for patients with metal device or medical implant. In contrast, CT often takes seconds or minutes, is cheaper and more available than MRI, and can be used safely on patients with implants.

A key disadvantage of CT is the relatively high levels of radiation required. As Pelc (2014) puts it, “an underlying principle of all X-ray imaging, and especially CT, is that we ‘pay for’ image quality with radiation dose.” Effective dose varies by procedure, patient size, CT system, and operating technique. The effective dose of a CT chest exam, for example, is about 350 times of a chest X-ray.

3.1 Over-radiation accidents, extensive media coverage, and subsequent events

In early October 2009, the Cedars-Sinai Medical Center in Los Angeles disclosed that it had mistakenly administered up to eight times the normal radiation to 206 patients undergoing CT brain perfusion because of erroneous scanner settings caused by hospital technicians. This accident received widespread media coverage together with a contemporaneous case in Northern California of a 2.5-year-old boy who was scanned for 68 minutes for a procedure normally taking a couple of minutes (Bogdanich, 2009). Since his first NYTimes article on these events in October 2009, Walt Bogdanich, by then a three-time Pulitzer Prize winner, did a series of reporting—titled “The Radiation Boom”—on medical radiation risk associated with imaging technologies as well as radiation therapies in a span of two years. Bogdanich was the 2011 Pulitzer Prize Finalist for “his spotlighting of medical radiation errors that injure thousands of Americans, sparking national discussion and remedial steps.”

Patients over-exposed to radiation at Cedars-Sinai filed a class action lawsuit against the hospital and the device manufacturer, GE Healthcare, in October 2009. Moreover, public concerns raised by these events led to a series of responses by regulators and the industry. In February 2010, the United States House of Representatives held a congressional hearing discussing the risk of medical radiation to the U.S. population. The testimonies by industry representatives emphasized innovations the industry had already introduced—such as weight and age-based protocols and automatic exposure control—that could help reduce the radiation doses while continually improving image quality; and that they were collaborating with various stakeholders, including the FDA, on measures to prevent future medical errors.

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2 Radiation therapies are very different from CT imaging technologies; they irradiated tumors with particle beams produced by linear accelerators.
The FDA initiated an immediate investigation of scanners involved in these events and held a public hearing on this issue in March 2010. The investigation revealed more wide-spread overexposure: as of October 26, 2010, the agency was aware of approximately 385 patients from six different hospitals who were exposed to excess radiation during CT brain perfusion scans; and the reported cases involved scanners manufactured by GE Healthcare and Toshiba America Medical Systems. This investigation concluded that these companies did not violate FDA laws and regulations. In particular, these scanners, if used according to the manufacturers’ specifications, would not result in overexposure. The investigation did, however, reveal improvements that the industry could make to its equipment, as well as user training. In November 2010, the FDA sent a letter to the Medical Imaging Technology Alliance (MITA), a leading industry association of medical imaging equipment manufacturers, with recommendations for safety improvement of their devices.

As a first response to these events, MITA published a technical standard known as the CT Dose Check (NEMA XR-25) in October 2010 that automatically checks for potentially high dose levels and notifies the CT operators. The CT Dose Check and another standard published in 2013 later became part of the MITA Smart Dose standard (NEMA XR-29, 2013).

3.2 Cancer risks of CT scans—scientific evidence and perception

Radiation concerns over CT scans arise because of the known association between ionizing radiation, such as X-ray, that damages DNA and the increased life time risk of developing cancer, especially for children and younger people. However, to establish a clear causal link between CT scans and excess cancer risk is challenging, given the lack of experimental variations (for obvious reasons) and the uncertainties associated with extrapolating estimates from other settings that involve doses higher than the diagnostic levels. Two approaches developed by the literature examining this issue are subject to these criticisms. One exploits estimates of organ-specific cancer risks derived from survivors of Hiroshima’s atomic bombing. Using this approach, Brennan and Hall (2007), whose study was published in The New England Journal of Medicine, conclude that about 1.5 to 2 percent of all cancers in the United States could be attributable to the clinical use of CT. The second type of studies follow cohorts of people who have undergone CT scans for a long period of time, and such studies just started around 2009.
Harbron (2016) summarizes seven papers published in recent years and suggests that, although subject to noisy measures and selection bias, the overall results appear to have strengthened the association between radiation exposure of CT and the risk of developing cancer; the effect appears to be small but statistically detectable, and the available evidence is stronger for some cancer sites (e.g., leukemia, thyroid, and breast) than others (e.g., bone and pancreas).

Anecdotal and survey evidence suggests that the overexposure accidents and their extensive media coverage have increased the awareness levels of both patients and medical providers about potential risks associated with CT. In a highly-cited study based on a 2002 survey of adult patients seen in the emergency department of a U.S. academic medical center, Lee et al. (2004) show that 47% of the radiologists and 9% of the emergency-room physicians believed that CT scans increased the lifetime risk of cancer; and roughly 75% of both groups significantly under-estimated the radiation dose from a CT scan. In contrast, Boutis, et al. (2014), based on a 2012 survey of pediatrician emergency medicine physicians in Canada, show that almost all responding physicians are aware of the potential malignancy risk from a head CT, and only 25% underestimated the associated radiation dose. For patients, Zwank, et al. (2014), using a 2010 survey of adult patients at a single tertiary care emergency department, show that 14.5% of the patients reported that their physicians discussed radiation risks with them, and 25% of the patients believed that radiation from CT can increase overall lifetime risk of cancer. These numbers are also significantly higher than those (7% and 3%, respectively) reported in Lee et al. (2004). Both studies conducted after 2010 refer to mass media coverage as among the likely reasons for the significant increase in patient and physician awareness.

Despite differences in their beliefs about the linkage between cancer risk and CT scans, the medical community generally agrees that CT should only be used when appropriate and with correct dose specifications (Thrall, 2012). According to Greg Freiherr (2010), these events seem to have also led to a fundamentally change to radiologists’ mindset—“from requesting the highest image quality to requesting ‘good enough’ images obtained with minimal radiation doses.” At the same time, the medical community also stresses not to lose sight of the contributions of CT to more effective surgeries, shorter hospital stays, elimination of exploratory surgery, and better diagnosis and treatment of cancer.

Interviews with anonymous industry sources suggest that before 2010, even though manufacturers
were conscious about safety in designing new CT systems, avoidance of over-radiation exposure was a secondary concern compared to the key objective of helping doctors “see more stuff.” As summarized in Pelc (2014), “historically, the main drivers for technological improvements have been the physicians’ demand for improved image quality, speed, and new clinical applications.” The events around 2010 made more prominent the goal of minimizing radiation exposure and may have influenced the direction of technological progress of CT and, likely, other diagnostic technologies using radiation.

4 Data and methods

We investigate the impacts of the series of events in late 2009 and 2010 (referred to as the ‘over-radiation shock’ thereafter) on a number of outcome variables, ranging from innovation by firms to equipment upgrade or replacement by hospitals and clinics and to the ordering of medical imaging services by physicians. This section describes the two datasets used to examine the impacts on innovation: (i) patent applications filed at and are eventually granted by the US Patents and Trademarks Office (USPTO), which capture patentable technologies close to their invention stage; and (ii) pre-market notifications submitted to and approved by the Food and Drug Administration (FDA) that measure new product introductions. We will provide details on the datasets for equipment replacement and use in section 7.

4.1 Patent applications

The USPTO assigns each patent to one or more technology classes following the Cooperative Patent Classification (CPC) scheme. Aggregation levels of CPC include sections (A), subsections (A61B), groups (A61B6), and subgroups (A61B6/10). We use the lowest level, CPC subgroups, and refer to them as patent subclasses. The data provided by the USPTO in July 2018 include 130,674 subclasses. Our analysis will mostly focus on the 140 subclasses covered by A61B6 “Apparatus for radiation diagnosis” that captures diagnostic devices using radiation, including standard X-rays and CT.

Based on the descriptions, we identify eight patent subclasses on technologies related to reducing radiation risk or other safety features. We refer to them as ‘risk mitigating technology’ (RMT) and allocate them into the treatment group. Two examples are A61B 6/542 “Control of devices for radiation diagnosis involving control of exposure” and A61B6/107 “Protection against radiation, e.g. shielding.”
The complete list of treated subclasses is provided in the data appendix with additional details on the selection process. In section 5, we will show that our results are robust to a different method, based on keyword match in patent titles, of defining treated subclasses.

The main control group in our patent analysis includes subclasses in A61B6 that are not classified as RMT (that is, non-RMT features of radiation diagnostic devices). In section 5.2, we examine the robustness of our findings to using alternative control groups including patent subclasses that are technologically more distant from the treatment group.

We assign patents to treatment versus control groups based on their primary CPC subclasses. In section 5.3, we provide a separate analysis utilizing patents’ secondary classifications. Because of grant delays, we date the patents using their application year rather than grant year. The first panel of Table 1 provides summary statistics of our main patent sample that spans 2005-2015. Patent data after 2015 are very sparse due to long grant delays. On average, there are 2.96 patent applications per year per subclass, and about 6 percent of the observations (subclass-year) belong to RMT subclasses.

4.2 FDA premarket notifications

The FDA classifies each device with a specific product code, which identifies the generic category of the device. CT scanners and other X-ray diagnostic devices are classified as class-II “moderate to high risk” devices. For such devices, a manufacturer intending to market in the U.S. must submit premarket notification (510k) to the FDA. There are approximately 1,700 unique product codes associated with class-II devices grouped into 19 medical specialties, including radiology. Our FDA sample is based on the 35,431 class-II 510k applications submitted between 2005 and 2017. Approval time of class-II devices is typically a few months, allowing us to extend the analysis until 2017.

The strength of the FDA data lies in the fact that they are about new product introductions and capture innovations that are not necessarily patentable. The challenge, however, is that each new product embodies various features, making it difficult to capture RMT features separately from the other features of a product as we can do with patents. As a result, our analysis of the FDA data is at the product level. We define a product code as treated if it involves radiology diagnostic devices

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that emit ionizing radiation. There are 19 treated product codes (1,242 applications), and examples include computed tomography (CT) X-ray system, emission computed tomography system (PET/CT), mammographic X-ray system, and diagnostic X-ray high voltage generator. In section 5.4, we explain additional data collection and analysis that help confirm that changes we detect are likely to be driven by innovations for risk-mitigating purposes.

The control group for our analysis of the FDA data includes product codes that are classified as radiology diagnostic devices but do not emit ionizing radiation as well as all class-II devices in non-radiology medical specialties such as cardiovascular, general and plastic surgery, and orthopedics. The dataset is a panel spanning 2005-2017 (we use the application year, not the decision year by the FDA), and it includes 1,477 product codes and 19,474 code-year observations. Summary statistics are presented in the second panel of Table 1. On average, there are 1.8 pre-market notifications per year in a product code.

4.3 Econometric model

Our empirical strategy relies on a standard difference-in-differences estimation:

\[ Y_{c,t} = \alpha + \beta Treated_{c} \times After2010_{t} + \delta_t + f_c + \varepsilon_{c,t}, \] (1)

where the dependent variable, \( Y_{c,t} \), captures innovation activities in technology area \( c \) and year \( t \). As explained above, the unit of the panel is subclass-year for the patent analysis, whereas for the FDA data, it is product code-year. The treatment group, \( Treated_{c} \), identifies technology areas that are expected to respond to the over-radiation shock. For patents, the treatment group includes technological features of radiation diagnostic devices that control radiation risk, whereas for the FDA data, it includes diagnostic devices in radiology emitting ionizing radiation. The dummy \( After2010_{t} \) equals 1 for every year after (and including) 2010; and \( \delta_t \) and \( f_c \) are year and technology area fixed effects. The coefficient \( \beta \) of the interaction term between \( Treated_{c} \) and \( After2010_{t} \) is the standard difference-in-differences estimator. We cluster the standard errors at the technology area level for all regressions.
4.4 Identification challenges

Identifying effects of the over-radiation shock presents a number of challenges. The first important concern is that the control group might be ‘contaminated’ in certain ways, and this could affect the interpretation of our estimated effect. On the supply side, for example, budget constraints may result in a decrease in investment in non-RMT areas if firms need to allocate more resources for RMT innovation. Alternatively, development efforts in RMT may induce firms to re-design their products overall, resulting in an increase of investment in control technologies. On the demand side, users may use diagnostic tools without radiation (e.g., MRI) more. This demand substitution may also increase investment in these alternative imaging technologies. For our purposes, we are less concerned about spillover effects that tend to increase investment in control technologies, as they are likely to result in an under-estimation of a positive effect of the shock on innovation activities in RMT and overall. On the other hand, spillover effects that decrease investment in control technologies are more worrisome, because they may lead to an over-estimation. In section 5.2, we provide robustness checks of our results against a number of different control groups, especially those that help mitigate concerns for potential over-estimation.

A second concern relates to the exogeneity of the shock and its timing. The accidental nature of these incidents and the rich documentation at the time on the responses of regulators and the industry association already provide quite convincing evidence for the exogeneity of the shock. Panel (a) of Appendix Figure A1 plots the timing of news articles referring to CT scan and X-ray radiation risk, retrieved from the Factiva (Dow Jones) database. The figure shows that following the first wave of reporting in October 2009, media coverage of radiation and dosage of imaging devices spiked in 2010. This also provides support for our choice of the treatment timing being around 2010. We provide two more pieces of evidence in support of this timing. Panel (b) of the same figure shows that the average number of months the FDA takes to approve an application increased substantially for radiation diagnostic devices after late 2009 relative to non-radiology class-II devices. Lastly, panel (c) plots the Google search trend for the term “CT Scan Radiation,” which also suggests that public interest became more intense after late 2009.

A third concern is about potential confounding factors. First, for instance, there could be concurrent
supply-side shocks such as scientific progresses or cost drops specifically related to RMT. As we discuss in details in section 7, an important type of response was the introduction of safety checks and dose displays that do not rely on scientific or cost breakthroughs. A substantial increase in this type of RMT after 2010 is not consistent with the idea that technology-specific supply shocks are the major driving force of our result. Second, demand shocks unrelated to the over-radiation shock may also potentially confound our estimates. For example, one may worry that investment in RMT is profitable only if the market is sufficiently large. Section 6.1 provides evidence against this alternative explanation, documenting how the overall technology use declined substantially after the over-radiation shock.

5 Innovation responses to the over-radiation shock

Figure 1 compares the average number of patent applications between RMT subclasses and control subclasses (i.e., other subclasses in radiation diagnostic devices ‘A61B6’) during our sample period. The figure shows that patenting in control subclasses is relatively stable throughout the period, whereas that in RMT subclasses is stable before 2009, drops slightly in 2009 and 2010, and increases substantially after 2010. While this figure provides a first look at our main result, we turn to regression analysis—first on the average effect of the over-radiation shock and then, in the next section, on pre-treatment trend and time-specific effects.

Table 2 presents the difference-in-differences estimates specified in equation (1). Column 1 shows that after 2010, patenting in RMT subclasses experienced an average increase of 1.78 patents per year relative to control subclasses (p-value is 0.029). Assuming the same average difference between the two groups before and after 2010, the ‘hypothetical’ average number of patents for RMT subclasses would have been 1.63 per year after 2010. This implies that the average increase in RMT patenting after 2010 is about 110 percent. Column 2 produces a similar estimate, dropping subclasses with zero patents during the entire sample period (about two percent of the observations). In column 3, following Moser and Voena (2012), we show that our baseline result is robust in an unbalanced panel that includes only observations for which we observe at least one patent in this particular subclass in previous years.

Because the over-radiation shock involves CT scanners, we expect the surge in RMT patenting to
be mostly driven by CT technology. Unfortunately, despite the detailed CPC classification system, we cannot cleanly distinguish patents related to CT scanners from other radiation diagnostic devices. One approach is to define CT patents as those referring to subclass A61B6/032 "Transmission computed tomography [CT]" either as primary or as secondary classification. This approach is likely to miss many patents related to components of CT technologies that may not refer to this subclass. The DID coefficient of this much smaller sample is reported in column 4 of Table 2. The estimate is economically large (corresponding to an increase of about 300 percent) with a p-value of 0.7. This result adds confidence to the interpretation of our baseline result that the increase in RMT innovation is related to the CT scanner over-radiation shock.

Appendix Table A1 reports additional robustness tests for our baseline regression. To address the skewed and count nature of our dependent variable, column 1 replaces the patent count with its logarithm transformation; column 2 uses a negative binomial estimation; and column 3 uses a Poisson quasi maximum-likelihood estimation. In all three specifications, we find a positive, large, and statistically significant DID coefficient. To account for heterogeneous sizes of different subclasses, column 4 uses a weighted regression, with each observation weighted by the (square root of) total patenting in the subclass during the pre-sample period of 1995-2004, and it shows a slightly stronger estimate. In column 5, we confirm our results using a block-bootstrapping estimation that maintains the autocorrelation structure within subclasses (as suggested by Bertrand et al., 2004). The standard errors are essentially identical to those estimated with our baseline clustering procedure, indicating that serial correlation is not a significant problem in our setting.

A potential concern is that RMT subclasses have been identified based on our subjective reading of the subclass description provided by the USPTO. As an alternative approach, we identify RMT subclasses using a textual analysis algorithm. We first construct a dictionary of keywords related to dose and radiation control (e.g., “dose control,” “reducing radiation,” and “x-ray intensity”). The full list of words is reported in the appendix. We then classify a patent as an RMT patent if its title contains at least one of the keywords. Finally, we compute the fraction of RMT patents in each subclass based on all patents in A61B6 applied (and granted) between 1975 and 2015. Column 1 of Appendix Table A2 confirms the results of Table 2, with eight treated subclasses defined as those in the top 5 percent of
the RMT fraction distribution. In column 2, we use the same definition of RMT subclasses as in column 1 but drop subclasses from the control group if more than two percent of their patents are RMT. The estimated coefficient is larger than, but not statistically different from, that in column 1. We then show that results are similar using the top 10 percent (15 subclasses; column 3) and the top 15 percent (22 subclasses, column 4). Once we relax the threshold to the top 20 percent (column 5), the coefficient becomes smaller and loses statistical significance.

5.1 Pre-treatment trend and time-specific treatment effects

In this section, we extend our baseline specification in equation (1) to estimate the year-specific differences between the treatment and control subclasses, \( \beta_t \). Specifically, we estimate:

\[
\text{Patents}_{c,t} = \alpha + \beta_t \text{RMT}_c \times \text{Year}_t + \delta_t + f_c + \varepsilon_{c,t},
\]

where 2009 is the baseline year.

Figure 2 provides a graphical illustration of the estimated coefficients and their 95-percent confidence intervals. Before the overdose accidents, the estimated differences between treatment and control subclasses are larger than but not statistically different from that in year 2009; the year-specific DID coefficients after 2010 are positive, increasingly larger, and become statistically significant in 2013.

We want to bring attention to two issues related to Figure 2. First, even though the coefficients for the years 2005-2008 are not statistically different from zero (that is, the baseline year 2009), the drop in 2009 breaks the stable pattern in prior years and seems non-trivial. This could be potentially concerning if the common-trend assumption is violated. One complication of assigning year 2009 to the pre-treatment regime is that the over-dose accidents were reported in early October that year; thus, the last quarter of 2009 is actually in the post-treatment period. If patenting actually declines immediately after the shock, we may observe a lower total patent counts in 2009. To further investigate this issue, we re-run equation (2) but count only patents in the first three quarters for each application year. This robustness check treats all years equally by including only patents applied in the first nine months and addresses the concern of 2009 straddling between the pre- and post-treatment regimes. The (unreported) estimated coefficients confirm that there is no evidence of a pre-trend.

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The second observation is that patenting in 2010 (the entire year is in the post-treatment period) is also lower than the average level of 2005-2008. This, together with the conjecture in the previous paragraph, also suggests that there may be some initial chilling effect on innovation (Galasso and Luo, 2018). This may happen if firms wanted to wait and see the conclusions of the FDA investigation and to rethink in which directions to further innovate to mitigate risk. Judging by Figure 2, the drop, even though may be present, is small and not statistically significant. To further provide an estimate of the longer-term effects of the over-radiation shock, we ran another variant of our baseline regression (1), dropping observations of 2009 and 2010. The DID coefficient shows a large and statistically significant increase of 2.06 patents per year in RMT subclasses relative to control subclasses after 2011.

5.2 Potential spillover effects on the control group

As discussed in section 4.4, a challenge with our identification strategy is that patenting in the control group may also have been affected by the over-radiation shock. Spillover effects that decrease investments in control technologies (e.g., firms facing fixed R&D budgets) are the most problematic because they can lead to an over-estimation of the positive effect of an increase in risk perception on RMT innovation. In the presence of such supply-side spillovers, our baseline estimates may capture a substitution between innovation in risk mitigating technologies and other research investments rather than an overall increase in innovation activities. In this section, we show that our main finding is robust to exploiting a variety of alternative control groups in which spillover concerns are less severe.

In column 1 of Table 3, we contrast our treatment group (i.e., RMT subclasses in radiation diagnostic devices) to a different control group consisting of non-radiation imaging technologies captured by two different CPC groups: (i) A61B5 "Detecting, measuring or recording for diagnostic purposes,” which includes diagnostic devices not using radiation or ultrasonic waves (e.g., MRI); and (ii) A61B8 “Diagnosis using ultrasonic, sonic or infrasonic waves.” This control group is technologically more distant from CT and, hence, may be less likely to experience supply-side substitution effect that we are most concerned about (e.g., because firms are different or if firms allocate research budgets and personnel relatively independently across technology groups). Indeed, only 1 percent of the assignees in A61B5 and 4 percent in A61B8 are also in our treatment group. To further mitigate the supply-side substitution
effect, we remove the common patentees—i.e., patentees active both in the treatment and in the control
technologies—from the control group only (column 2) and from both the control and the treatment
groups (column 3). In all three columns, the DID coefficients are slightly smaller, but statistically
similar to, our baseline estimate in column 1 of Table 2.

The last three columns of Table 3 replicate the first three columns, but use patent subclasses related
to medical implants—CPC subsection ‘A61F.’ These patent classes relate to devices placed inside or
on the surface of the body, such as replacement joints, intraocular lenses, and heart valves, which are
technologically very different from CT scanners. The results across all columns are consistent with our
baseline conclusion. The difference in the magnitudes between our baseline estimate and the smallest
coefficient of Table 3 (column 6) can provide an upper bound to the impact of the shift in patenting
from non-RMT to RMT subclasses. This approach suggests that such substitution may account for, at
most, 31 percent of the total effect indicated by our baseline.

Demand-side spillover may also be at play if the shock induced hospitals and clinics to increase
the use of diagnostics tools without radiation (e.g., MRI). Such contamination is less concerning, as it
leads to greater innovation in alternative technologies that would make our estimate more conservative.
Furthermore, demand-side spillover is likely to be very limited for the estimates in columns 4-6 in Table
3 that use medical implants as the control group.

5.3 Secondary classifications of patents

Previous analysis allocates patents to treatment and control groups based on their primary subclasses.
Even though a patent can be assigned to only one primary class (based on its main inventive concept),
it can be assigned to multiple secondary classifications if it also relates to other inventive concepts. In
fact, a vast majority of patents (90 percent) applied between 2005 and 2015 in radiation diagnostic
devices (A61B6) have at least one secondary subclass; the average is 4.7 and the median is 4. In this
section, we focus on patents’ secondary classes and examine whether risk mitigation has become a more
prominent feature for radiation diagnostic devices more generally after 2010; that is, even though not
the primary goal, risk mitigation may be part of the invention.

The raw data show that in the period 2005-09, about 9 percent of the patents in A61B6 list an RMT
subclass as a secondary classification (but not as the primary classification), whereas 19 percent do so between 2010 and 2015. Furthermore, the unique number of primary subclasses for which an RMT subclass is listed as a secondary classification by at least one patent increases from 52 to 93, suggesting that risk mitigation has become a more prevalent feature across different types of diagnostic devices that use radiation.

Table 4 presents a series of patent-level regressions estimating the following linear probability model:

\[ \text{SecondaryRMT}_{itcj} = \beta_0 + \beta_1 \text{Year}_t + \beta_2 N_{\text{Second}}_i + \beta_3 N_{\text{Claims}}_i + \kappa_c + \nu_j + \epsilon_{itcj}, \]

where \( \text{SecondaryRMT}_{itcj} \) is a dummy that equals one when patent \( i \) with application year \( t \), primary subclass \( c \) and owned by firm \( j \) lists at least one risk-mitigating subclass as secondary subclass. The dummies \( \text{Year}_t \) are the coefficients of interest—they capture the application year effects with 2009 as the baseline. The sample is cross-sectional and includes all the patents in A61B6 with a non-RMT primary subclass. The regressions control for the number of secondary subclasses of a patent, \( N_{\text{Second}}_i \), which is important because the propensity to have an RMT subclass as secondary classification mechanically increases with the number of secondary subclasses. The regressions also include the number of claims in the patent, \( N_{\text{Claims}}_i \); primary subclasses effects, \( \kappa_c \); and patent owner (assignee) effects, \( \nu_j \).

Column 1 estimates the above specification without including primary subclass or assignee fixed effects; column 2 includes primary subclass fixed effects; and column 3 includes both primary subclass and firm fixed effects. Across all specifications, the application-year coefficients before 2010 are small (both positive and negative) and statistically insignificant. After 2010, the application-year coefficients are all positive, and the magnitude increases substantially over time (except for the last year 2015). These results confirm our baseline result that patents filed after the over-radiation shock are substantially more likely to include risk-mitigating features in the invention. Finally, column 4 replicates column 3 but uses only the subset of patents that refer to CT class (A61B6/032) as either primary or secondary classification. The sample size drops substantially, which is likely the reason for the noisier estimates, but the magnitudes of the application-year coefficients are similar to column 3.

Overall, results in this section provide further support for the idea that risk-mitigating technologies became a more prominent goal of research activities after the over-radiation events. In the next section,
we further explore this issue by looking at the FDA data on new product introductions.

### 5.4 Analysis of FDA pre-market notifications

In this section, we present difference-in-differences results on new product introductions based on the FDA data. As we discussed in Section 5.2, it is challenging to separately measure specific features of a new product. Thus, our analysis is at the product level. We will exploit detailed information in the application summary file to identify those products in which risk mitigating components play a prominent role.

The dependent variable in column 1 of Table 5 is the number of 510k applications in a given product code-year. Our treatment group includes the 19 product codes of radiology diagnostic devices that emit ionizing radiation, and the control group includes non-radiation radiology diagnostic devices and all class-II devices outside radiology. The result shows that after 2010, the average number of applications by treated devices increased by 1.25 per year relative to the control group (p-value is 0.07). This increase represents a 30-percent difference, assuming the same difference between the treatment and control devices before and after 2010.

In columns 2 and 3, we run the same regression and use the same control group as in column 1 but focus on two specific sub-samples of the treatment group. In particular, column 2 excludes from the treatment group devices emitting high levels of radiation, whereas column 3 excludes devices emitting low levels of radiations. While the coefficients of the two columns are not statistically different from each other, the substantially greater magnitude and higher statistical significance level of the DID coefficient in column 3 is consistent with the idea that the increase in applications documented in column 1 is more likely to be driven by devices more affected by the over-radiation shock.

For further evidence that the increase in applications for treatment group is, indeed, linked to the over-radiation shock, we further identify applications that emphasize safety features. In particular, for each of the 1,242 applications in the treatment group, we search for the keyword ‘dose’ in the “Summary of Safety and Effectiveness,” a document that includes the description of the device, indication of use, and the comparison to predicate devices. Example phrases including this keyword are ‘dose check,’ ‘dose efficiency,’ and ‘dose reduction.’ Overall, 18 percent of the 1,242 applications include this keyword. The
regression in column 4 counts only the number of applications in a treated product code that do not mention 'dose' in their summary files, and column 5 counts only applications that do; and the dependent variable of the control group is the same as previous columns. The coefficient in column 4 is small and statistically insignificant, whereas that in column 5 is large and significant at the 0.05 level. This contrast further corroborates the idea that the relative increase in radiation diagnostic devices is associated with a stronger emphasis on dose control.

As in the patent analysis, the 2010 shock may also affect some of our control devices. In column 6, we exclude non-ionizing radiology diagnostic devices that may experience potential demand substitution from the control group. The estimate confirms the result in column 5. Based on the sample of column 6, Figure 3 examines the timing of the effect of the 2010 shock. There is no evidence of pre-trends: the coefficients before 2010 are small and statistically insignificant. The increase in applications with ionizing radiation including safety features begins to increase after 2010, with an increasing magnitude over time.

Overall, the FDA data show an increase in the number of new products after 2010 for diagnostic devices emitting ionizing radiation, and this increase is driven by applications explicitly referring to radiation control. It is worth noting that because there is typically a delay between invention and commercialization, the relative fast response in product introduction (as illustrated in Figure 3) suggests that the product is likely to be based on non-patentable technologies (therefore, not captured by the patent data) or on patentable technologies that were readily available prior to 2010. In section 7, we provide a more-detailed investigation of CT technologies that shed light on this interpretation.

6 Demand effects of an increase in risk perception

Our analysis of the patent and FDA data shows that the 2010 over-radiation shock led to a significant increase in innovation activities—specifically the development of risk-mitigating features for radiation diagnostic devices. In principle, innovation activities could increase for a number of reasons. In this paper, we highlight one particular channel: an increase in perceived risk of the product that affects its demand. In section 3, we discuss a variety of evidence from survey studies and industry sources
suggesting that this effect played an important role. In this section, we provide more direct evidence for this mechanism by unbundling the shock’s impact on demand.

Theoretically, an increase in the perceived risk of a product may have an ambiguous effect on its demand. On the one hand, greater perceived risk may induce hospitals and physicians to reduce the use of the technology, which could lead to a decline in the demand for new devices. On the other hand, the increased willingness to pay for safety features could increase the demand for new, safer devices.

This section provides evidence for these effects. At the intensive margin, we examine how the number of imaging services provided changes after the over-radiation shock; and at the extensive margin, we examine the changes in frequency of equipment upgrade and replacement. Specifically, we show that, after 2010, there is a sharp decline in the number of high-radiation imaging services performed. This, however, is accompanied by a greater propensity to upgrade equipment emitting high levels of radiation. We discuss how these two effects may be separately explained by other demand shifters, but their joint presence suggests that the increase in risk perception plays a prominent role.

6.1 Equipment use

To the best of our knowledge, comprehensive datasets on the usage of diagnostic imaging services are not available. To address this challenge, we exploit data provided by Medicare, a federal health insurance program covering people who are 65 or older. Medicare Part B National Summary Data provide the total number of services rendered (and processed) to Medicare beneficiaries during a calendar year at the procedure level. Procedures are identified by ‘current procedural terminology’ (CPT) codes. The codes specify the technology type, organ or body part, and techniques of an exam (e.g., CT chest without contrast).

There are 725 unique CPT codes recorded in the Medicare data between 2005 and 2017 that pertain to diagnostic radiology. With descriptions of CPT codes licensed from the American Medical Association, we are able to categorize 696 codes into seven technology types such as CT and MRI. This covers 89.7 percent of the total number of services in 2005-2017. To construct a balanced panel, we keep codes that are present throughout the 13 years, which leaves 438 codes corresponding to 70 percent of the total number of services. The final balanced panel dataset includes 5,694 year-procedure observations.
Appendix figure A2 presents the average number of services per procedure by technology type between 2005 and 2017. The most salient observation from the raw data is the sharp drop in the average number of CT exams after 2011, which persists for the duration of our sample. In contrast, non-radiation technologies—MRI and ultrasound—either exhibit no change or increase after 2010; and low-radiation X-ray services also experience no change before and after 2010. Other high radiation procedures either cease to grow after 2010 (PET) or exhibit a slight and gradual decrease (fluoroscopy and nuclear medicine).

Table 6 presents the difference-in-differences coefficients for the number of services provided, controlling for CPT and year fixed effects. Columns 1 and 2 compare high-radiation procedures (including CT, PET, fluoroscopy, and nuclear medicine) to low-radiation standard X-rays. The dependent variable of column 1 is the number of services, while its logarithmic transformation is the dependent variable of column 2. Consistent with our analysis of innovation measures, the post period is defined as after (and including) 2010. The results show that, relative to X-rays, the average number of high-radiation procedures drops substantially after 2010 (by about 56.3 percent). Columns 3 and 4 replicate the first two regressions but use non-radiation procedures—MRI and ultrasound—as the control group; and the estimated decrease is at 52.4 percent. The last two columns replicate columns 2 and 4 but use only control procedures that match treated procedures in terms of pre-trends. These produce estimates similar to using unmatched controls.

Based on the sample used in column 6, Appendix figure A3 plots the year-specific effect of the overdose shock on high-radiation procedures relative to matched control procedures of MRI and ultrasound. The results show little pre-trend, a slight drop in 2010 (p-value is 0.115), and a sharp decline starting from 2011 that never recovers as of 2017.

6.2 Equipment upgrade

The key data source used in the analysis of equipment upgrade or replacement is the X-ray assembler dataset provided by the FDA. The data provide information on the location of the equipment, its intended use (e.g. CT whole body scanner, mammography, chest, and urology) as well as a list of the installed components (e.g. X-ray control, high voltage generator, film charger).
A key limitation of this dataset is that it contains only X-ray equipment and lacks non-radiation equipment such as MRI or ultrasound. We address this challenge by comparing the propensity to upgrade CT equipment to that of chest X-ray and dental X-ray equipment. This approach is consistent with the fact that radiation exposure from CT is substantially greater than standard X-rays and is in line with our finding that low radiation X-ray devices are less affected by the shock. Another limitation of the data is that for confidentiality reasons, they do not contain information on whether the assembly report is for installation of a new system or for replacement of a component in the existing system. To address this issue, we exploit the available information on components installed in order to identify reports that are likely about assembly of new CT systems or substantial upgrades of existing CT systems. Specifically, we identify reports where the intended use of the components is “CT whole body scanner” and where the installation involves at least 3 major components (X-ray control, high voltage generator and tube housing). With a similar approach, we identify records that are likely to capture replacement or substantial upgrades of non-fluoroscopic chest and dental X-ray systems. The final sample is based on 6,161 CT system assembly reports, 4,389 chest X-ray and 2,246 dental X-ray system assembly reports for 2008-18 (data before 2008 are not systematically available).

We generate a balanced panel, where the unit of observation is a site-device type-year. Appendix Figure A5 plots the frequency of assembly reports for CT, dental X-ray, and chest X-ray equipment in the raw data over time. The CT and chest series appear to have very similar trends up to 2012, but the frequency of new CT scanners increases substantially in the last period of the sample. Similarly, the difference between new dental and CT systems increases significantly after 2012.

Moving to a regression framework, column 1 of Table 7 contrasts the number of assembly reports on CT systems versus chest X-ray systems, controlling for year and clinic-device type fixed effects. The result illustrates that, within a clinic, the propensity to replace or upgrade a CT system after 2010 exceeds that for a chest X-ray system; and the magnitude of the DID coefficient is equivalent to a 25-percent higher upgrade/replacement likelihood. Column 2 shows a similar result contrasting CT systems with dental X-ray systems. Columns 3 and 4 confirm these findings with linear probability

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4 Sites (hospitals or clinics) are defined as unique combinations of firm name, city and state in which the equipment is installed.
models, in which the dependent variable is a dummy equal to one if the location assembled at least one device for the specific device type.

6.3 Discussion

To summarize the results in this and the previous sections, after the 2010 over-radiation shock: (i) the use of high-radiation imaging services, CT in particular, experienced a sharp and large decline; (ii) hospitals increased their propensity to upgrade and replace their CT systems; and (iii) firms increased innovation aimed at mitigating radiation risk.

The joint presence of a decline in usage and an increasing propensity to upgrade equipment is consistent with the anecdotal and survey evidence discussed in section 3 that describe a significant increase in users' perceived risk of CT. In isolation, the drop in usage can be explained by a number of demand or supply shifters such as a decline in the number of patients or a technological breakthrough in alternative technologies. Similarly, a higher propensity to upgrade equipment can potentially be explained by an increase in demand for superior image quality, by lower production costs, or by positive financial shocks affecting hospitals. These alternative explanations, however, are not consistent with the joint presence of these two offsetting effects on demand.

Overall innovation incentives are likely to depend on the combined effect of the drop in usage and the increase in the demand for safer devices. In our context, the positive effect from a greater demand for safer devices appears to have dominated (at least in the short run) the negative effect on overall usage. More generally, our analysis indicates that the link between innovation and risk perception depends on the complex responses of market demand.

Interestingly, the large magnitude of the drop in usage is consistent with the claim in Brennen and Hall (2007) that “roughly 30 percent of CT procedures are not necessary.” If it is, indeed, true that the reduction was mostly due to uncritical use, the radiation scare may have provided some sort of re-alignment of the incentives between physicians and their patients. In other words, physicians and hospitals might have had a propensity to over-test prior to 2010, and this may have been reduced due to the increase in perceived radiation risk (partly due to concerns over patients’ accumulative radiation exposure and partly due to liability concerns over misuse). Potential reasons for over-testing may have
included financial motives or fear of medical malpractice liability, which results from not doing enough to care for the patient (often labeled as ‘defensive medicine’). Assessing the interplay between these various incentives, though beyond the scope of this paper, is an interesting topic.

Lastly, it is remarkable to see that despite the innovation response, the use of CT does not recover in the duration of our sample period. It is possible that it is still too soon to observe a positive impact of safety innovation on the use of CT, and it is also hard to gauge what the counterfactual usage level might have been in the absence of safety-related innovations. However, if the low level of CT use sustains in the long run, it is possible that hospitals may start to demand CT scanners that require less upfront investment or find ways to consolidate the number of machines purchased, which would, similarly, reduce upfront investment. These actions, in turn, may further influence firms’ innovation activities.

7 Characterizing RMTs: the case of CT scanners

In section 5, we document a link between the over-radiation shock and the increase in innovation activities using aggregate data on patents and FDA applications. In this section, we complement that analysis by providing a detailed characterization of the nature of RMTs. This account focuses on CT scanners and combines information from field interviews, industry and clinical publications, and textual analysis of FDA application summary files.

As we will explain in detail below, we uncover two types of RMTs that were developed after the shock: (i) improvements along the existing, dominant technological path; and (ii) technologies which rely on fundamentally different scientific principles, representing a substantial change in the technological path. The former type of change was recommended by regulators and has been implemented through a series of new standards set by the industry. Meanwhile, the latter went way beyond the required level, and reflects the notion that market demand for safer machines played an important role in selecting the direction of technological progress. It is important to distinguish these different types of responses. They also relate to important concepts proposed by the literature that include the distinction between technological paradigms and trajectories proposed by Dosi (1982); dominant designs (Utterback and Abernathy, 1975); and technological discontinuities (Anderson and Tushman, 1990).
7.1 Progress along the dominant technological path

One type of RMTs developed by CT scanner producers appears to tackle ‘low-hanging fruits’ in the sense that the goal of the improvement is to prevent radiation over-dose or to manage dosage more efficiently, without a substantial departure from existing technologies. These innovations, though important and likely to make a meaningful difference, do not require substantial R&D investment. An example is the redesign of displays to show technologists the level of radiation before the scan begins (Mayo-Smith et al., 2014). Other examples are alert systems that warn operators when scan settings exceed pre-assigned dose thresholds; software that records post-exam dose information in a standardized electronic format; and redesigned use protocols for certain procedures (Mahesh, 2016).

The industry rapidly adopted these safety-check features through a series of new standards set by the industry association. The nature of these safety checks is consistent with the complaints in lawsuits brought by over-irradiated patients and the FDA’s recommendations after concluding the investigation of the over-radiation events.5

A natural question is why these safety checks were not developed before the shock. A potential explanation is that, though seemingly easy to develop, these safety checks may impose non-trivial costs to manufacturers and users of CT scanners. For example, once an alert is triggered, the system requires a facility supervisor to enter a diagnostic reason and passcode in order to proceed with the exam. This additional step may disrupt the facility’s work-flow. Furthermore, how reference values are set and who sets them may have implications for the allocation of liability in the case of negative events.6

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5 For example, plaintiffs in a lawsuit claimed that the devices “failed to contain adequate or proper warnings concerning the defective condition, characteristics, and health risks associated with said products.” Trevor Rees vs. Cedars Sinai Medical Center, GE Healthcare, Inc., a Delaware corporation, et al. Case number BC424189, October 19, 2009, Superior Court of California, County of Los Angeles.

6 These concerns may be reflected in how the standards evolve over time: in the 2010 NEMA XR-25 standard, the manufacturers gave the operators the option, but not the obligation, to set notification and alert values; furthermore, it was also the operators who decided on the thresholds, not the manufacturers. In 2013, NEMA XR-28 was published in response to a list of suggestions by the FDA, and these new standards required that the dose check alert and notification values be pre-populated by the manufacturers.
7.2 Change in technological path

Another type of RMT differs qualitatively from what we describe in the previous section: it involves a substantial departure from the existing technological trajectory and allows for a reduction in radiation dose of up to 80-90 percent (depending on the procedure and the technology), which is not achievable by simply ‘tweaking’ the existing technologies. Briefly, the change involves shifting away from the previous, dominant method of image reconstruction—i.e., the process through which the acquired X-ray data are translated into three-dimensional image data—that underlies the strong dependency of image quality on radiation dose. After the over-radiation shock, CT manufacturers started to develop a previously shelved methodology that breaks this dependency and, as put by GE Healthcare, “establishes new rules in the relationship between image quality and dose reduction.”

For over 30 years, the dominant method of image reconstruction had been filtered back projection (FBP). Simply speaking, FBP is a ‘linear’ method that projects X-ray data directly into image data (Ramirez-Giraldo et al., 2018). Although FBP is fast and robust, its image resolution (in terms of absence of noise) is strongly dependent on the amount of dose used which, hence, established the ‘old’ rule of CT imaging—“we ‘pay for’ image quality with radiation dose” (Pelc, 2014). An alternative approach, called ‘iterative reconstruction (IR),’ starts with an initial guess of an object and iteratively improve on the initial estimate through a dynamic optimization process (Mayo-Smith et al., 2014). This ‘non-linear’ methodology breaks the strong dependence of noise on radiation dose and, therefore, allows for substantial reductions in radiation dose (Pelc, 2014). IR was first introduced when CT was invented in the seventies. The reason why FBP, instead, became the dominant method is because of its drastically lower computational intensity: IR took about 45 minutes to reconstruct just a single slice given the computing speeds at that time; while FBP could process slices in 30 seconds.7

Our interviews with industry practitioners, along with rich documentation by industry white papers and clinical publications, suggest that CT manufacturers invested in and marketed IR algorithms heavily after the over-radiation shock. As we will show later in the next section, about half of the CT systems introduced after 2010 included an IR option.

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It is important to note that IR algorithms involved substantial reduction in other quality aspects, at least initially. First, even with the immense advances in computing power, the speed of IR still lags behind relative to that of FBP. For example, the typical speed for FBP is 2.9-6.6 images per second, the IR speed equals 0.2-0.5 images per second (Ginat and Gupta, 2014; Geyer et al, 2015). Such a long reconstruction time (ranging between 10 to 90 minutes) may not be suitable for emergency patients and could negatively impact clinical practice. Second, in clinical applications with low contrast detectability such as abdominal and brain CT examinations, the image quality generated by IR is substantially inferior to that by full-dose FBP. Lastly, IR images appear ‘over-smoothed,’ with an ‘artificial’ and ‘blotchy’ appearance that may be difficult to interpret and require re-training of radiologists (Raman et al., 2013; Ramirez-Ghiraldo et al, 2018). In the few years after the shock, we have already witnessed three generations of IR algorithms, each improving upon the previous in either speed or other aspects of image quality, including mimicking the image texture to that of a full-dose FBP image to make the images easier to read by radiologists.

Overall, the fast integration of IR methodology into new CT systems and its rapid iteration, despite the sacrifice in speed or other aspects of image quality, is consistent with the increased demand for safer machines that we have documented in previous sections and is corroborated by various industry accounts (Freiherr, 2010; Ramirez-Ghiraldo et al, 2018). Finally, it is important to note that while the development of safety checks discussed in the previous section was also suggested by the FDA and standardized by the industry association, this was not the case for the development of IR algorithms that were driven by firms’ independent research programs. This distinction mitigates the concern that the innovation response to the over-radiation shock was mostly driven by interventions of the regulator, rather than a shift in demand and consumer preferences.

7.3 FDA application data

To provide quantitative evidence for the two types of safety features described above, we conduct a textual analysis using the 294 FDA applications filed between 2005 and 2017 in product code JAK “Computed tomography x-ray system.” These applications include new CT systems and software packages that complement existing CT systems. For each application, we examine all phrases in the summary
of the safety and effectiveness information that include the term ‘dose’ and determine, based on keywords used together with ‘dose,’ whether the product (i) achieves a dose reduction relative to previous products; and/or (ii) provides safety checks or tools to manage radiation dose more efficiently. Furthermore, we define a product as adopting the IR methodology if the summary file contains the keyword “iterative reconstruction” or other trade names that companies use for such algorithms.

Panel A of Appendix figure A5 plots the percentage of the applications in a given year that contain dose-efficiency or dose-check features, and panel B plots the percentage containing dose-reduction features. The figures show that both types of safety features were rarely mentioned in the application summary files before 2010, whereas they are increasingly more likely to appear afterwards. Between 2014 and 2017, for example, 37.5 percent of all applications mention dose check or efficiency, and 25 percent mention dose reduction. The lower level of dose-reduction features is consistent with the notion that they require more substantial investment than features related to dose efficiency or dose check.

Panel C of the same figure illustrates an increasing adoption of the IR method after 2010. Overall, 52 percent of all CT systems adopted after 2010 include an IR option and 20 percent of the software packages are specifically about this method. Moreover, the data show that all 118 applications after 2010 without an IR option fail to mention dose reduction; whereas 38 out of 66 applications (58 percent) that include an IR option do mention the term. This contrast is consistent with our understanding that substantial dose reduction is only achievable with the IR methodology.

8 The role of large incumbents

In this section, we examine the extent to which the increase in RMT innovation—both at the invention and the commercialization stages—is driven by large incumbents firms versus smaller players in the industry. This analysis may provide further insights into the nature of RMTs and how shocks related to product safety may affect the dynamics of competitive advantage and market structure.

In particular, we distinguish between two groups of firms—top five firms versus smaller players, which includes relatively small firms, new entrants, individuals, and research entities. The top five firms are Toshiba, Siemens, Hitachi, GE, and Philips. These firms have the highest number of patents in
radiation diagnostic devices during the pre-sample period 1995-2005; in addition, these five firms were major CT manufacturers and comprised the CT group of the industry association MITA at the time of the shock (NEMA, 2010).

Columns 1 and 2 of Table 8 report the DID regression results of the effect of the over-radiation shock on patenting for these two groups of patentees. The coefficients show that about one third of the aggregate increase in patent applications after 2010 is driven by the top five firms while the rest is driven by smaller patentees. The estimates are less precise than those reported in Table 2 (p-values are 0.07 and 0.10, respectively), and we cannot reject equality between the two coefficients. Relative to the patenting rates in RMT subclasses before 2010, the increase in patenting is about 75 percent for the top five firms and 140 percent for smaller patentees. For new product introduction, columns 3 and 4 show that FDA applications by the top five firms explain 44 percent of the aggregate increase after 2010; and relative to the pre-shock levels, the increase is about 40 percent for the top five firms and 24 percent for smaller patentees. Finally, Appendix figure A6 shows that large and small firms appear similar in their responses through incremental features such as safety checks and dose efficiency management, but responses by large firms are faster and more intense for more complex technologies such as the development and implementation of iterative reconstruction algorithms.

Overall, analysis by firm size illustrates the following patterns: (i) innovation activities in RMTs are economically substantial for both the largest firms and smaller patentees; and (ii) relative to the patenting stage, the largest firms seem to play a more prominent role than the smaller patentees at the commercialization stage. These patterns seem to suggest that the over-radiation shock may have perpetuated the market dominance of large incumbents, rather than diminishing it. The following discusses potential explanations based on the nature of safety-related demand shocks and the characteristics of the market.

First, information shock on product safety is likely to exhibit a negative externality and affect the entire product category—in particular, the demand of mainstream customers served by large incumbents. In other words, the condition often characterized in theories such as disruptive innovation—that is, the innovation is initially not valued by mainstream customers—is not satisfied in our context (Christensen and Bower, 1996). Second, the types of RMTs described in section 7 do not fit in a situation in
which incumbent firms are less competent to respond in terms of organizational capabilities or resources (Henderson and Clark, 1990). In contrast, large incumbents in our setting are well-positioned, in terms of R&D resources and marketing and distribution capabilities, to develop and incorporate these RMTs into their products. Lastly, the fact that the response from smaller patentees is also economically substantial is consistent with a well-functioning market for technologies in which knowledge can be transferred to firms with manufacturing and commercialization assets (Gans and Stern, 2000; Arora, Fosfuri and Gambardella, 2004).

9 Conclusions

In this paper, we examine the relationship between risk perception and innovation, taking advantage of a series of unexpected CT scan over-radiation accidents that took place in the U.S. in late 2009.

Our empirical analysis illustrates an increase in patenting on features of radiation diagnostic devices that mitigate radiation risk relative to patenting on other features, on the order of 110 percent. We also document an increase in the number of new product introductions using the FDA data and confirm that this increase is driven by products for which radiation control features are prominent. Consistent with the idea that these investments are driven by changes in risk preferences of the users, we find that the over-radiation shock led to a shift in demand characterized by the following features: (i) a decrease at the intensive margin (i.e., fewer procedures performed); and (ii) an increase at the extensive margin (i.e., greater propensity to upgrade the equipment). Focusing on CT scanners, we further document two different types of RMTs, encompassing both minor improvement of existing technologies and a substantial re-direction of technological trajectory.

Ultimately, our analysis suggests that changes in risk perception can be an important driver of innovation and shape the direction of technological progress. Changes in risk perception have ambiguous impacts on the demand for a technology, and in settings such as ours, the potential positive effect may dominate their chilling effect. Furthermore, large players tend to play an important role in the development of these RMTs, especially in their commercialization, which has important implications for the dynamics of competitive advantage and market structure.
References


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Figure 1: Patenting in RMT subclasses vs. other subclasses in radiation diagnostic devices

Notes: Average number of patents in risk-mitigating technology subclasses versus other subclasses in radiation diagnostic devices (that is, CPC group A61B6).
Figure 2: Dynamic effects of the over-radiation shock on patenting

Notes: Year-specific DID coefficients estimated from equation (2). The treatment group includes RMT subclasses and the control group includes other subclasses in radiation diagnostic devices (that is, CPC group A61B6).
Figure 3: Dynamic effects of the over-radiation shock on FDA pre-market notifications

Notes: Year-specific DID coefficients estimated from a specification analogous to equation (2). The treatment group includes all product codes of diagnostic devices in radiology that emit ionizing radiation, and the control group includes all product codes of class-II devices in non-radiology medical specialities. The model includes year and product code fixed effects.
Table 1. Summary statistics

<table>
<thead>
<tr>
<th></th>
<th>Obs.</th>
<th>Mean</th>
<th>Std. Dev.</th>
<th>Min</th>
<th>Max</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Patent applications</strong></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Patents</td>
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<td>2.962</td>
<td>6.185</td>
<td>0</td>
<td>97</td>
</tr>
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<td>Year</td>
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<td>3.163</td>
<td>2005</td>
<td>2015</td>
</tr>
<tr>
<td>Risk Mitigating Technology Class</td>
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<tr>
<td><strong>FDA applications</strong></td>
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<td></td>
<td></td>
<td></td>
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<tr>
<td>Applications</td>
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<td>1.819</td>
<td>5.327</td>
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</tr>
<tr>
<td>Year</td>
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<td>2011</td>
<td>3.742</td>
<td>2005</td>
<td>2017</td>
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<tr>
<td>Ionizing Radiation Codes</td>
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<td>0.013</td>
<td>0.112</td>
<td>0</td>
<td>1</td>
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</table>

Patents = the number of patent applications in a subclass-year. Risk Mitigating Technology = 1 for subclasses reducing the risk of over-radiation, controlling the level of patient exposure, and detecting faults or malfunctions. Applications = number of class II 510k applications in the product code-year. Ionizing Radiation Codes = 1 for product codes related to radiology diagnostic devices emitting ionizing radiations.
<table>
<thead>
<tr>
<th>Dependent variable</th>
<th>(1)</th>
<th>(2)</th>
<th>(3)</th>
<th>(4)</th>
</tr>
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<tbody>
<tr>
<td>RMT x After 2010</td>
<td>1.783**</td>
<td>1.785**</td>
<td>2.650**</td>
<td>0.727*</td>
</tr>
<tr>
<td></td>
<td>(0.809)</td>
<td>(0.814)</td>
<td>(1.166)</td>
<td>(0.402)</td>
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<td>Year effects</td>
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<td>YES</td>
<td>YES</td>
<td>YES</td>
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<tr>
<td>Subclass effects</td>
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<td>YES</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>Estimation</td>
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<td>OLS</td>
<td>OLS</td>
<td>OLS</td>
</tr>
<tr>
<td>Note</td>
<td>Baseline</td>
<td>Drop if all zeros</td>
<td>Start at first patent</td>
<td>Only CT patents</td>
</tr>
<tr>
<td>Observations</td>
<td>1540</td>
<td>1507</td>
<td>1001</td>
<td>1540</td>
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</tbody>
</table>

Robust standard errors clustered at the subclass level. *significant at 10 percent, ** significant at 5 percent and *** significant at 1 percent. Patents = the number of patent applications in a subclass-year. RMT =1 for patent subclasses involving risk mitigating technologies. Column 4 CT patents refer to subclass A61B6/032 as primary or secondary class.
<table>
<thead>
<tr>
<th>Dependent variable</th>
<th>(1)</th>
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<th>(3)</th>
<th>(4)</th>
<th>(5)</th>
<th>(6)</th>
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</thead>
<tbody>
<tr>
<td>Risk Mitigating Tech X After 2010</td>
<td>1.522** (0.719)</td>
<td>1.690** (0.719)</td>
<td>1.544* (0.963)</td>
<td>1.229* (0.720)</td>
<td>1.424** (0.720)</td>
<td>1.224** (0.492)</td>
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<tr>
<td>Control Group</td>
<td>A61B5 and A61B8</td>
<td>A61B5 and A61B8</td>
<td>A61B5 and A61B8</td>
<td>A61F</td>
<td>A61F</td>
<td>A61F</td>
</tr>
<tr>
<td>Drop overlapping patentees</td>
<td>NO from control</td>
<td>from treatment and control</td>
<td>NO from control</td>
<td>from treatment and control</td>
<td></td>
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<td>Year effects</td>
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<td>YES</td>
<td>YES</td>
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OLS regressions with robust standard errors clustered at the subclass level. * significant at 10 percent, ** significant at 5 percent and *** significant at 1 percent. Patents = the number of patent applications in a subclass-year.
Table 4. Secondary patent classes

<table>
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<td>Dependent variable</td>
<td>at least one RMT secondary subclass</td>
<td>at least one RMT secondary subclass</td>
<td>at least one RMT secondary subclass</td>
</tr>
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<td>-0.014</td>
<td>-0.008</td>
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</tr>
<tr>
<td></td>
<td>(0.020)</td>
<td>(0.021)</td>
<td>(0.034)</td>
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<tr>
<td>Year 2006</td>
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<td>-0.001</td>
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<tr>
<td></td>
<td>(0.020)</td>
<td>(0.020)</td>
<td>(0.031)</td>
</tr>
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<td>Year 2007</td>
<td>-0.018</td>
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<tr>
<td></td>
<td>(0.020)</td>
<td>(0.020)</td>
<td>(0.030)</td>
</tr>
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<td>-0.017</td>
<td>-0.028</td>
</tr>
<tr>
<td></td>
<td>(0.020)</td>
<td>(0.020)</td>
<td>(0.030)</td>
</tr>
<tr>
<td>Year 2010</td>
<td>0.031</td>
<td>0.040*</td>
<td>0.044</td>
</tr>
<tr>
<td></td>
<td>(0.023)</td>
<td>(0.023)</td>
<td>(0.033)</td>
</tr>
<tr>
<td>Year 2011</td>
<td>0.058**</td>
<td>0.063***</td>
<td>0.063*</td>
</tr>
<tr>
<td></td>
<td>(0.023)</td>
<td>(0.024)</td>
<td>(0.036)</td>
</tr>
<tr>
<td>Year 2012</td>
<td>0.085***</td>
<td>0.094***</td>
<td>0.097***</td>
</tr>
<tr>
<td></td>
<td>(0.024)</td>
<td>(0.024)</td>
<td>(0.037)</td>
</tr>
<tr>
<td>Year 2013</td>
<td>0.090***</td>
<td>0.111***</td>
<td>0.100**</td>
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<tr>
<td></td>
<td>(0.027)</td>
<td>(0.027)</td>
<td>(0.040)</td>
</tr>
<tr>
<td>Year 2014</td>
<td>0.120***</td>
<td>0.143***</td>
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<tr>
<td></td>
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<td>(0.027)</td>
<td>(0.043)</td>
</tr>
<tr>
<td>Year 2015</td>
<td>0.059*</td>
<td>0.075**</td>
<td>0.033</td>
</tr>
<tr>
<td></td>
<td>(0.033)</td>
<td>(0.032)</td>
<td>(0.050)</td>
</tr>
<tr>
<td>Number of secondary subclasses</td>
<td>0.016***</td>
<td>0.017***</td>
<td>0.020***</td>
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<tr>
<td></td>
<td>(0.002)</td>
<td>(0.002)</td>
<td>(0.003)</td>
</tr>
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</tr>
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<td>Observations</td>
<td>4,131</td>
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<td>4,131</td>
</tr>
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</table>

Patent level regressions. Sample includes all patents in A61B6 with primary subclass that is not an RMT. Dependent variable =1 if patent lists at least one RMT subclass as secondary subclass. Robust standard errors * significant at 10 percent, ** significant at 5 percent and *** significant at 1 percent. Year 2009 is the baseline year.
<table>
<thead>
<tr>
<th>Dependent variable</th>
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<th>(3)</th>
<th>(4)</th>
<th>(5)</th>
<th>(6)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ionizing radiology device</td>
<td>1.250* (0.690)</td>
<td>0.871 (0.873)</td>
<td>1.900* (1.076)</td>
<td>0.234 (0.580)</td>
<td>1.091** (0.442)</td>
<td>1.102** (0.441)</td>
</tr>
<tr>
<td>Year FE</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>Product code FE</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
</tr>
</tbody>
</table>

Control group
- Non-ionizing and non-radiology devices
- Non-ionizing and non-radiology devices
- Non-ionizing and non-radiology devices
- Non-ionizing and non-radiology devices
- Non-radiology devices

Sample
- Full
- Only low radiation devices in treatment group
- Only high radiation devices in treatment group
- Full
- Full
- Drop non-ionizing radiology devices from control group

Observations | 19474 | 19383 | 19318 | 19474 | 19474 | 18876 |

Robust standard errors clustered at the product code level. * significant at 10 percent, ** significant at 5 percent and *** significant at 1 percent. Apps = the number of FDA applications in a subclass-year. In column 4 the dependent variable only counts ionizing radiology applications not containing the word 'dose' in the summary files. In columns 5 and 6 the dependent variable only counts ionizing radiology applications containing the word 'dose' in the summary files. Ionizing radiology device =1 for product codes related to radiology devices emitting radiation.
Table 6. Equipment usage in Medicare data

<table>
<thead>
<tr>
<th>Dependent Variable</th>
<th>(1)</th>
<th>(2)</th>
<th>(3)</th>
<th>(4)</th>
<th>(5)</th>
<th>(6)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treated procedures *</td>
<td>7120.591</td>
<td>-0.501***</td>
<td>14722.906*</td>
<td>-0.482***</td>
<td>-0.600***</td>
<td>-0.461***</td>
</tr>
<tr>
<td>After 2010</td>
<td>(8902.015)</td>
<td>(0.104)</td>
<td>(7545.508)</td>
<td>(0.103)</td>
<td>(0.134)</td>
<td>(0.121)</td>
</tr>
<tr>
<td>Year effects</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>CPT effects</td>
<td>Y</td>
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<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>Control group</td>
<td>low radiation</td>
<td>low radiation</td>
<td>MRI and ultrasound</td>
<td>MRI and ultrasound</td>
<td>Matched low radiation</td>
<td>Matched MRI ultrasound</td>
</tr>
<tr>
<td>Observations</td>
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<td>3536</td>
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<td>2886</td>
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<td>2340</td>
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</table>

OLS regressions with robust standard errors clustered at the CPT level. * significant at 10 percent, ** significant at 5 percent and *** significant at 1 percent. Services = number of medicare services reported for the procedure in a given year.
### Table 7. Equipment upgrade

<table>
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<th>Dependent variable</th>
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<tbody>
<tr>
<td></td>
<td>Assembly reports</td>
<td>Assembly reports</td>
<td>Assembly dummy</td>
<td>Assembly dummy</td>
</tr>
<tr>
<td>CT Scanners X After 2010</td>
<td>0.004*** (0.001)</td>
<td>0.003*** (0.001)</td>
<td>0.003*** (0.001)</td>
<td>0.005*** (0.001)</td>
</tr>
<tr>
<td>Control Group</td>
<td>Chest</td>
<td>Dental</td>
<td>Chest</td>
<td>Dental</td>
</tr>
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<td>Year effects</td>
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<td>YES</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>Site-equipment type effects</td>
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<td>YES</td>
<td>YES</td>
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<td>Observations</td>
<td>715330</td>
<td>715330</td>
<td>715330</td>
<td>715330</td>
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</table>

OLS regressions with robust standard errors clustered at the site (clinic or hospital) level. * significant at 10 percent, ** significant at 5 percent and *** significant at 1 percent. Assembly reports = the number of assembly reports related to a specific equipment type in the site-year. Assembly dummy = 1 if at least one assembly report in equipment type-site-year.
Table 8. Heterogeneous effects by firm size

<table>
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<tr>
<th>Dependent Variable</th>
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<th>(4)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Patents by top 5 firms</td>
<td>Patents by other firms</td>
<td>FDA Applications by top 5 firms</td>
<td>FDA Applications by other firms</td>
</tr>
<tr>
<td>RMT x After 2010</td>
<td>0.600* (0.337)</td>
<td>1.183 (0.722)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ionizing radiology device x After 2010</td>
<td></td>
<td></td>
<td>0.549* (0.329)</td>
<td>0.701 (0.591)</td>
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<tr>
<td>Year effects</td>
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<td>YES</td>
<td>YES</td>
<td>YES</td>
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<tr>
<td>Subclass effects</td>
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<td>NO</td>
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<td>Product code effects</td>
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<tr>
<td>Observations</td>
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<td>1540</td>
<td>19474</td>
<td>19474</td>
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<tr>
<td>Baseline</td>
<td>0.791</td>
<td>0.854</td>
<td>1.370</td>
<td>2.926</td>
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</table>

OLS regressions with robust standard errors clustered at the subclass or product code level. * significant at 10 percent, ** significant at 5 percent and *** significant at 1 percent. Patents = the number of patent applications in a subclass-year. RMT = 1 for patent subclasses involving risk mitigating technologies. Ionizing radiology device = 1 for product codes related to radiology devices emitting ionizing radiation. Top 5 firms: Toshiba, Hitachi, GE, Siemens, and Phillips. Baseline: average number of patents or FDA applications for treatment group before 2010.