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JEL Classification: O31, O32, O34, K13

Keywords: risk perception, Innovation, medical devices, product liabilities

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Risk-Mitigating Technologies: the Case of Radiation Diagnostic Devices*

Alberto Galasso† Hong Luo‡

April 12, 2019

Abstract

We study the impact of consumers' risk perception on firm innovation. Our analysis exploits a major surge in the perceived risk of radiation diagnostic devices, following extensive media coverage of a set of over-radiation accidents involving CT scanners in late 2009. Difference-in-differences regressions using data on patents and FDA product clearances show that the increased perception of radiation risk spurred the development of new technologies that mitigated such risk and led to a greater number of new products. We provide qualitative evidence and describe patterns of equipment usage and upgrade that are consistent with this mechanism. Our analysis suggests that changes in risk perception can be an important driver of innovation and shape the direction of technological progress.

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1 Introduction

At least since Schmookler (1966), strategy, innovation, and economics scholars have emphasized the links between market demand, innovation incentives, and technological progress. The broad consensus is that market demand plays a crucial role in selecting from among the potential alternative 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 may steer technological progress through a variety of mechanisms. These include: market size (Acemoglu and Linn, 2004; Costinot, et al., forthcoming); heterogeneity in consumer needs (Adner and Levinthal, 2001); knowledge regarding local demand patterns (Fabrizio and Thomas, 2012); and feedback from customers and lead users (von Hippel, 1986; Chatterji and Fabrizio, 2012). Despite this extensive literature, shifts in demand driven by the perception of risk in using a product have, thus far, received little empirical and theoretical attention. Our paper fills this gap by examining firms' innovation responses to a significant change in perceived product safety and by characterizing the nature of the resulting innovations.

Health and safety concerns are of first-order importance in many aspects of our lives. With product liability accounting for the majority of civil personal injury cases in the U.S. (70 percent in 2016, for example), such concerns are critically important to firms that produce these products. Moreover, prominent product failures tend to attract extensive media coverage and public attention—such as the fatal accident in March 2018 involving Uber's autonomous vehicle and the recent Boeing 737 MAX crashes in Indonesia and Ethiopia—and such attention can have profound impacts on the perceived safety level of the underlying technologies.

Changes in risk perception potentially differ from other demand-pull forces in a number of dimensions. First, consumers rarely have the full information about risk, and their learning process is typically subject to biases, such as the over-weighting of small-probability events and events that have been highly publicized (Lichtenstein et al., 1978; Slovic et al., 1982). Second, the impact of risk perception on product demand and, hence, innovation incentives is potentially ambiguous. On the one hand, the overall demand for the product is likely to drop, especially with large upward changes in the perceived

risk. On the other hand, the willingness to pay for safety features and safer products will increase (Viscusi, 1993). Third, changes in risk perception may exhibit externalities that potentially affect the entire product category. As a result, negative events may have far-reaching impact beyond firms that are directly involved (Jarrell and Peltzman, 1985), and their impact on innovation activities is also likely to be shaped by non-market forces such as regulation, the liability systems, and standard-setting organizations (Viscusi and Moore, 1993; Barnett and King, 2008; Berrone et al., 2013; Galasso and Luo, 2017, 2018). These features of risk perception may have important implications for the direction of technological progress, competitive advantage, and market structure.

We define innovations that reduce the probability of negative events and/or the severity of the consequences as risk-mitigating technologies (henceforth, RMTs). RMTs may take various forms, ranging from incremental to radical innovations (Henderson, 1993) and from process to product innovations (Cohen and Klepper, 1996). To examine the incentives to develop RMTs, our paper 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 dose to over 200 patients undergoing CT brain perfusion because of erroneous scanner settings caused by the hospital. We document a variety of evidence based on industry accounts, congressional hearings, surveys, and field interviews, suggesting that the extensive media coverage of this and other overdose accidents uncovered at the time increased patients' and medical providers' perceived risk of CT and other radiation-emitting technologies.

Our empirical analysis proceeds in multiple steps. We begin with an examination of the shock's impact on firm innovation in terms of both patenting and new product introductions. For patenting, we leverage the detailed patent classification system to define RMTs—that is, patent subclasses related to technologies aimed at protecting against radiation, controlling the level of radiation 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) are likely to be moderate. This implies an overall increase in innovation in radiation diagnostic devices.

Using FDA data on pre-market notifications, we show that the over-radiation shock also led 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 two findings: 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: the over-radiation shock led to an increase in users' perceived risk of CT scans, which, in turn, affected demand. In particular, we show that demand changed at two different margins. In terms of technology use (the intensive margin), we show that the number of services rendered for diagnostic procedures involving high radiation experienced a large and sharp drop after 2010. In terms of technology upgrade (the extensive margin), however, we find that, after the shock, hospitals' and clinics' propensity to replace or upgrade CT systems increased significantly relative to equipment emitting lower levels of radiation. The joint presence of a decline in usage and an increase in equipment upgrade is consistent with an increase in risk perception and is hard to reconcile with alternative mechanisms.

We further complement our aggregate, quantitative analysis with an in-depth characterization of the nature of these RMTs. Specifically, we document two types of RMTs. The first type can be thought of as 'low-hanging fruit,' 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 alerts and notification systems, are implemented by the CT industry through a series of new standards set by the industry association. The second type of RMTs is qualitatively different because it requires a substantial departure from the method that has 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 evidence is consistent with the idea that market demand can play a role in the selection and establishment of dominant designs (Utterback and Abernathy, 1975) or technological paradigms (Dosi, 1982).

We conclude our empirical analysis by examining the role of large firms in the development of RMTs. We show that (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 play a more prominent role in the commercialization stage. The latter result is especially true for the type of RMTs that require substantial R&D investment. These patterns are consistent with the idea that the shock affected the entire product category and that dominant players were better equipped to incorporate new technologies into new products. These results also suggest that the over-radiation shock 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 discusses the theoretical insights that guide our empirical analysis. Section 4 provides background information on CT and the over-radiation shock. Section 5 describes the data and our empirical approach. Section 6 presents the empirical results linking the shock to innovation measures using patent and FDA data. Section 7 reports results on demand changes in terms of equipment upgrades and their usage. Section 8 focuses on CT scanners and provides a characterization of different types of RMTs, and section 9 discusses the role of large incumbents and smaller players. Section 10 concludes.

2 Related literature

Our paper is related to studies that investigate the relationship between tort liability risk and innovation. Despite much theoretical and policy attention (Huber, 1989; Porter, 1990; Daughety and Reinganum, 1995; Hay and Spier, 2005; Parchomovsky and Stein, 2008), large-sample empirical evidence on this topic is scarce. Examining a sample of large U.S. manufacturing firms in the 1980s, Viscusi and Moore

(1993) find a positive relationship between product liability insurance costs and R&D expenditure. Their results suggest that, on average, product liability promotes rather than discourages innovation. Galasso and Luo (2017) re-examine this issue and also find a positive relationship between liability risk and innovation; in particular, they show that, on average, states passing tort reforms that decrease physicians' exposure to medical malpractice liability are associated with a significant decrease in medical-device patenting. Theoretical frameworks in both papers show offsetting effects of higher liability risks on innovation: on the one hand, higher liability risks may chill the development and adoption of innovation due to higher costs and uncertainties; on the other hand, they may also incentivize the development of safer products or complementary technologies that reduce the likelihood and severity of injuries. Galasso and Luo (2018) exploit a major quasi-exogenous increase in liability risk faced by US suppliers of polymers used to manufacture medical implants. In contrast to previous studies, they find a large and negative impact on downstream innovation in medical implants. Galasso and Luo (2018) argue that an unexpected, substantial surge in liability faced by large upstream general-purpose input suppliers may restrict supply or even foreclosure to downstream markets with the greatest risks, and such supply restriction may negatively affect downstream innovation. This paper makes two contributions to the understanding of liability risk and innovation. First, while Viscusi and Moore (1993) and Galasso and Luo (2017) suggest that liabilities may incentivize the development of risk-mitigating technologies, neither paper directly measures this type of innovation. This paper characterizes and measures risk-mitigating technologies and provides direct evidence for a change in the direction of innovation. Second, we show that even in the absence of changes in the liability rules, changes in risk perception of a product may impact the effective liability risk faced by both the producers and users (CT scanner producers and hospitals/physicians, respectively, in our setting) of the product, leading to changes in technological development and industry standards.

More broadly, our analysis relates to the vast economics and management literatures on the determinants and directions of technological change. Ahuja, et al. (2008), Cohen (2010), and Di Stefano, Gambardella and Verona (2012) provide comprehensive overviews of the academic debate 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 in addressing

these issues and providing new evidence for the linkages between market demand and innovation (Sutton, 1998; Acemoglu and Linn, 2004; Finkelstein, 2004). While most of these studies have focused on market size and factor prices, the economics and strategy literatures on the environment have examined the innovation responses to climate change and natural disasters (Miao and Popp, 2014; Popp, 2019), as well as to regulatory and normative pressures (Berrone et al., 2013). We contribute to this line of research by examining the innovation impacts of demand shifts driven by increases in the risk perception of product use.

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 beliefs about the safety of the product category. Using sales or stock price data, the literature produces mixed results on the existence of such a spillover effect (e.g., Jarrell and Peltzman; 1985; Hoffer et al., 1988). Later studies focusing on the mechanisms find that the spillover effect is more likely to be present when consumers' prior of rival firms' product safety is less precise, which, in turn, depends on factors such as the stringency of government regulation and the development stage of an industry, as well as whether firms share common practices (Borenstein and Zimmerman, 1988; Freedman et al., 2012). Dranove and Olsen (1994) provide a supply-side explanation for a negative effect on rival firms' market value: concerns about more-stringent FDA regulation that is costly for firms. We add to this literature by exploring accidents that are likely to increase the perceived risk of the entire category and show that the innovation response is industry-wide. It is worth noting that there are no product recalls in our setting, as the accidents are caused by user errors. This allows us to also study the response of the producers directly involved, with limited concern about the direct costs of product recalls, such as legal and financial losses. The only paper we are aware of that studies the impacts of product recalls on innovation is Ball et al. (2018), which is also in the context of medical devices. They show that product recalls have negative impacts on innovations of focal firms (likely due to financial and operational disruptions) but positive effects on their rivals (likely due to competitive effects). Our paper is different from theirs in terms of the nature of the shocks, our focus on innovations that specifically address safety concerns, and the underlying mechanisms.

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 by providing evidence that links liability concerns with medical technology development, adoption, and usage.

3 Theoretical considerations

Risk perceptions may have important impacts on consumer choices, especially when markets fail to provide full insurance against uncertainty (Arrow, 1970). In the context of product safety, one can think of the risk associated with the use of a product as the probability of a negative event and the severity of the consequences (e.g., minor injuries, major injuries, or even death). Such negative events may occur to the user of the product directly or to a third party for which the user of the product bears the cost indirectly, such as through legal liabilities.

Often, consumers do not have precise risk information, and their choices of products to purchase and their intensity of use are based on the consumers' perception of risk. Risk perception evolves as new information is revealed over time through, for example, personal experience, news reporting of accidents, and publication of new scientific studies. This new information can serve as either good news or bad news, leading to an upward or downward revision in risk perception, depending on how the new information compares to consumers' prior belief. The magnitudes of these revisions depend on the precision of consumers' prior belief and the precision of the new information. Thus, a couple of fatal accidents may result in large downward revisions about risk associated with emerging technologies, such as driverless cars, but may have little influence on consumers' assessment of products for which rich statistical data are available. Two commonly cited results in the risk perception literature are that individuals tend to over-assess the risks of low-probability events and under-assess the risks of high-probability events (Lichtenstein et al., 1978; Tverskey and Kahneman, 1982); in addition, some of the over-assessed risks are those that have been highly publicized (Slovic et al., 1982). These patterns of risk assessment are shown to be consistent with a Bayesian learning process even with fully rational

agents, unless they acquire full information about the riskiness of the product (Viscusi, 1985).

Learning about risk implies that informational shocks that increase the risk that consumers perceive about a product may generate shifts in market demand. In particular, consumers' willingness to pay for risk reduction will increase (Viscusi, 1993). If this increase in willingness to pay for safety is sufficiently large, demand changes may serve as a "pull" force for innovation and incentivize the development of RMTs (Schmookler, 1966). Conceptually, RMTs reduce the probability of negative events and/or the severity of the consequences. Seatbelts and airbags, for example, reduce the risk of fatal accidents in automobiles. Often, RMTs involve tradeoffs between different characteristics of a product. For example, installing a speed limiter on a motorcycle reduces the likelihood of serious accidents but also reduces the pleasure that some consumers derive from high speed. As we will explain in detail later, one type of RMT that addresses the increased perception of radiation risk requires certain sacrifices in the speed and quality of CT images.

RMTs may take various forms, depending on the nature of the hazards, the magnitudes of the demand changes, the technological possibilities, and the associated development costs. They can be incremental or modular innovations that refine existing technologies or radical innovations that may establish new, dominant designs (Utterback and Abernathy, 1975; Dosi, 1982; and Anderson and Tushman, 1990). Moreover, while many examples of RMTs are product innovations, process innovations—e.g., new features of an assembly line that are more effective at identifying product defects—can also be RTMs (Cohen and Klepper, 1996).

The impact of increased risk perception on product demand and, hence, overall innovation incentives, is potentially ambiguous. Within a set of existing products, higher perceived risk is likely to reduce demand for riskier products and increase it for safer ones; but if this substitution is limited, the overall demand for the product category is likely to drop. The development of RMTs may partially, or completely, offset the demand drop, depending on how the safety of the new products incorporating RMTs is perceived. In the case of durable goods, we also need to distinguish demand at two different margins—the purchase of the products and the intensity of use. When it is not easy for the users to consolidate use or to find substitute products, we may observe an increase in the demand for products incorporating RMTs, despite a lower intensity of use. For example, a substantial increase in the per-

ceived risk of automobile crashes may lead consumers to replace their cars with safer models and to drive their new cars less often. These opposite effects at the intensive and extensive margins would not be present in the canonical case of quality-enhancing product innovation.

Finally, information shocks such as accidents and product failures may exhibit externalities that can impact the entire product category or even related categories. For instance, new information revealing widespread failures of hip implants may increase the risk perception of all implanted medical devices (breast implants, pacemakers, etc.). Uber's fatal accident killing a pedestrian in March 2018 led not only Uber, but also other companies, such as Toyota, to pause public road testing immediately afterwards.[1] Such externality has important implications for risk perception, learning, and innovative responses. First, we may expect that innovative responses will likely come from firms beyond the focal firms directly implicated by the negative events. Second, this process is also likely to be shaped by non-market forces such as regulators, standard-setting associations, consumer-protection groups, and legal liability systems. Third, large firms may play an important role in the development of RMTs both because accidents are more likely to involve products of firms with the largest market share and because large firms are more likely to internalize the externalities affecting the entire product category.

4 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 dramatic increase from about three million in 1980 (Brenner 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

[1] Source: "Toyota Takes Self-Driving Cars Off Road After Uber Accident," Neal E. Boudette, March 20, 2018, NYTimes, https://www.nytimes.com/2018/03/20/business/uber-driverless-car-accident.html.

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 implants and pacemakers. 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, "[A]n 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 dose of a CT chest exam, for example, is about 350 times that of a chest X-ray.[2]

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

In early October 2009, the Cedars-Sinai Medical Center in Los Angeles disclosed that, due to erroneous scanner settings, it had mistakenly administered up to eight times the normal radiation to 206 patients undergoing CT brain perfusion. The error had been made a year prior to the disclosure, when the hospital had reconfigured a scanner to improve doctors' ability to see blood flow in the brain.[3] These accidents received widespread media coverage, together with coverage of a contemporaneous case in Northern California of a 2.5-year-old boy who was scanned for 68 minutes for a procedure normally taking only a few minutes (Bogdanich, 2009). Following his first *New York Times* article on these events in October 2009, Walt Bogdanich, by then a three-time Pulitzer Prize winner, wrote a series of reports in the span of two years. Titled "The Radiation Boom," the series reported on the medical radiation risk associated with imaging technologies and radiation therapies.[4] Bogdanich was a 2011 Pulitzer Prize finalist for "his spotlighting of medical radiation errors that injure thousands of Americans, sparking national discussion and remedial steps."[5]

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

[2] U.S. Food and Drug Administration, "What are the Radiation Risks from CT?" https://www.fda.gov/radiation-emittingproducts/radiationemittingproductsandprocedures/medicalimaging/medicalx-rays/ucm115329.htm.

[3] Alan Zarembo, "Cedars-Sinai radiation overdoses went unseen at several points," Los Angeles Times, October 14.

[4] Radiation therapies are very different from CT imaging technologies; they irradiate tumors with particle beams produced by linear accelerators.

[5] Source: www.pulitzer.org/finalists/walt-bogdanich.

to the U.S. population. The testimonies by industry representatives emphasized innovations that the industry had already introduced—such as weight- and age-based protocols and automatic exposure control—that could help reduce the radiation dose; they also testified that they were collaborating with various stakeholders, including the FDA, on measures to prevent future medical errors.

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 widespread 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 had not violated FDA laws and regulations. In particular, it concluded that these scanners, if used according to the manufacturers' specifications, would not result in over-exposure. The investigation did, however, suggest improvements that the industry could make to its equipment and 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 improving the safety 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).

4.2 Cancer risks of CT scans—scientific evidence and perception

Radiation concerns about CT scans arise because of the known association between ionizing radiation, such as X-ray, that damages DNA and the increased lifetime 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. The literature has examined this issue exploiting survivors of Hiroshima's atomic bombing (Brenner and Hall, 2007) or following cohorts of people who have undergone CT scans for a long period of time (Harbron, 2016). These studies are subject to criticisms, including selection bias, measurement error, and uncertainty associated with extrapolating estimates from other settings that

involve doses higher than the diagnostic levels. These caveats notwithstanding, the overall assessment is that an association exists between radiation exposure from CT and the risk of developing cancer and that the effect appears small but statistically detectable (Harbron, 2016).

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 the 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 underestimated the radiation dose from a CT scan. In contrast, Boutis, et al. (2014), based on a 2012 survey of pediatric 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.

Reacting to these series of events, the medical community stresses that we should not 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. At the same time, it agrees that CT should be used only when appropriate and with correct dose specifications (Thrall, 2012). According to Freiherr (2010), the radiation overdose events seem to have also led to a fundamental change in radiologists' mindset—"from requesting the highest image quality to requesting 'good enough' images obtained with minimal radiation doses."

Interviews with anonymous industry sources suggest that before 2010, even though manufacturers were conscious of 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 emphasized the goal of minimizing radiation exposure and may have influenced the direction of the technological progress of CT and, likely, other diagnostic technologies using radiation.

5 Data and methods

We investigate the impacts of the series of events in late 2009 and 2010 (referred to as the 'over-radiation shock' hereafter) on a number of outcome variables, ranging from innovation by firms, to equipment upgrade 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 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 upgrade and use in section 7.

5.1 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 focus mainly on the 140 subclasses covered by A61B6, "Apparatus for radiation diagnosis," which captures diagnostic devices using radiation, including standard X-rays and CT.

Based on the class descriptions provided by the USPTO, we identify eight patent subclasses of technologies related to reducing radiation risk or other safety features. We refer to them as RMT subclasses and allocate them to 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 6, we will show that our results are robust to a different

method of defining treated subclasses, based on keyword matches in patent titles.

The main control group in our patent analysis includes subclasses in A61B6 that are not classified as RMTs (that is, non-RMT features of radiation diagnostic devices). In section 6.2, 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 6.3, we provide a separate analysis utilizing patents' secondary classifications. Because of grant delays, we date the patents using their application year rather than their grant year. The first panel of Table 1 provides summary statistics of our main patent sample, which 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 six percent of the observations (subclass-year) belong to RMT subclasses.

5.2 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.[6] 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. In section 6.4, we explain additional data collection and analysis that help confirm that changes we detect are likely to be driven by products for which RMTs are prominent features.

We define a product code as treated if it involves radiology diagnostic devices that emit ionizing

[6] Source: www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM284443.pdf.

radiation.[7] 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.

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); it includes 1,477 product codes and 19,474 code-year observations. On average, there are 1.8 pre-market notifications per year in a product code (second panel of Table 1).

5.3 Econometric model

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

$$Y_{c,t} = \alpha + \beta Treated_c \times After2010_t + \delta_t + f_c + \varepsilon_{c,t}, \tag{1}$$

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 δ_t and f_c are year and technology area fixed effects. The coefficient β 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.

[7] We identify diagnostic devices based on the regulation numbers associated with each product code. For radiology, see https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=892. Furthermore, information on whether devices in a product code emit radiation and on the type of radiation (e.g. ionizing, optical, microwave or acoustic) is provided by the FDA Radiation-Emitting Electronic Product Codes Database.

5.4 Identification challenges

Identifying the 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 redesign their products overall, which may actually result 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 underestimation of a positive effect of the shock on innovation activities in RMTs and overall. In contrast, spillover effects that decrease investment in control technologies are more worrisome because they may lead to an overestimation. In section 6.2, we provide robustness checks of our results against a number of different control groups, especially those that help mitigate concerns about potential overestimation.

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 of the regulator's and industry association's responses 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, relative to control devices, the average number of months that the FDA took to approve an application increased substantially for radiation diagnostic devices starting from the fourth quarter of 2009. This is consistent with the idea that the regulator scrutinized these devices more after 2010. 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. For instance, there could be concurrent supply-side shocks, such as scientific progress or drops in the costs specifically related to RMT. As we discuss in detail in section 8, an important type of response was the introduction of safety checks and dose displays. These are relatively inexpensive technologies that do not rely on scientific 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. Demand shocks unrelated to the over-radiation shock may also potentially confound our estimates. For example, one may worry that investment in RMTs is profitable only if the market is sufficiently large. Section 7.1 provides evidence against this alternative explanation, documenting how the overall use of the technology declined substantially after the shock.

6 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 was relatively stable throughout the period, whereas patenting in RMT subclasses was stable before 2009, dropped slightly in 2009 and 2010, and increased substantially after 2010. While this figure provides a first look at our main result, we turn to regression analysis below—first, on the average effect of the over-radiation shock and then, in the next section, on the 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 was about 110 percent.[8] Column 2 produces a similar estimate, dropping subclasses with zero patents

[8] The average number of patents for non-RMT subclasses after 2010 is 2.92, and the pre-2010 difference between RMT and non-RMT subclasses is -1.29 patents per year.

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 driven mostly by CT technology. We define CT patents as those referring to subclass A61B6/032 "Transmission computed tomography [CT]" either as primary or as secondary classification. 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 0.07. This result adds confidence to our interpretation that the increase in RMT patenting is related to the CT scanner over-radiation shock.[9]

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 difference-in-differences coefficient.[10] 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 larger 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 interpretation 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 exposure"). The full list of keywords is reported in the appendix. We then classify a patent as an RMT patent if its title contains

[9] To account for the large number of zeros in this smaller sample, we re-estimated the regression with a Poisson specification. The difference-in-differences coefficient is 1.368 and significant at the 0.01 level.

[10] Quantitatively, the implied elasticities range from 0.54 to 1.45, a range that is in line with our baseline estimates.

at least one of the keywords. Finally, we compute the fraction of RMT patents in each subclass based on all patents in A61B6 applied 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 five percent of the RMT fraction distribution. In column 2, we use the same definition of RMT subclasses as in column 1, but we drop subclasses from the control group if more than two percent of their patents are RMTs. The estimated coefficient is larger than, but not statistically different from, that in column 1. We then show that results are similar if we define the treatment group as including those in the top ten percent of the RMT fraction distribution (15 subclasses; column 3) and top 15 percent (22 subclasses; column 4). Once we relax the threshold to the top 20 percent (column 5), the difference-in-differences coefficient becomes smaller and loses statistical significance.[11]

6.1 Pre-treatment trend and time-specific treatment effects

Results in the previous section show that the over-radiation shock increased innovation activities substantially in RMT subclasses. In this section, we estimate the year-specific differences between the treatment and control groups, β_t. Specifically, we estimate:

$$Patents_{c,t} = \alpha + \sum_t \beta_t RMT_c \times Year_t + \delta_t + f_c + \varepsilon_{c,t}, \tag{2}$$

where 2009 is the baseline year.

Figure 2 provides a graphical illustration of the estimated coefficients and their 95-percent confidence intervals. Before the over-radiation shock, the estimated differences between treatment and control subclasses are not statistically different from those in 2009; the year-specific difference-in-differences coefficients after 2010 are positive and increasingly larger, and they become statistically significant in 2013.

We want to bring attention to two issues related to Figure 2. First, even though the coefficients for 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

[11] The results in Appendix Table A2 are similar using a Poisson model. Furthermore, if RMT patents are defined by finding a keyword match in titles as well as in abstracts, the estimated coefficients are of similar magnitudes but less precisely estimated (p-values in regressions analogous to columns 1-3 of Appendix Table A2 range from 0.06 to 0.14).

common-trend assumption is violated. One complication of assigning 2009 to the pre-treatment regime is that the overdose accidents were reported in early October that year; thus, the last quarter of 2009 is actually in the post-treatment period. If patenting in RMT subclasses actually declined immediately after the shock, we may observe a lower total patent count in 2009. To further investigate this issue, we rerun 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 it addresses the concern of 2009 straddling the pre- and post-treatment regimes. The (unreported) results confirm that there is little concern for any pre-trend (that is, the coefficients for 2005-2008 are economically very small).

The second observation is that patenting in 2010 (the entire year is in the post-treatment period) was also lower than the average level of 2005-2008. This, together with the conjecture in the previous paragraph, also suggests that there may have been some initial chilling effect on innovation. This might have happened if firms wanted to wait for the conclusions of the FDA investigation as they considered the directions in which to further innovate to mitigate risk. Judging by Figure 2, the drop, even though present, was 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 from 2009 and 2010. The result shows a large and statistically significant increase of 2.06 patents per year in RMT subclasses after 2011 relative to the level in 2005-2008.

6.2 Potential spillover effects on the control group

As discussed in section 5.4, 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 RMTs 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 for which such spillover concerns are more limited.

In column 1 of Table 3, we contrast our treatment group (i.e., RMT subclasses in radiation diagnostic devices) with 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 the supply-side substitution effect that most concerns us (e.g., because firms are different or if firms allocate research budgets and personnel relatively independently across technology groups). Indeed, only one percent of the assignees in A61B5 and four percent in A61B8 also patent in our treatment group. To further mitigate the supply-side substitution effect, we remove the common patentees—i.e., patentees active in both the treatment and control groups—from the control group only (column 2) and from both the control and the treatment groups (column 3). In all three columns, the estimated coefficients are slightly smaller, but statistically similar to, our baseline estimate in column 1 of Table 2.[12] Note that demand-side spillover may also be at play if the shock induced hospitals and clinics to increase the use of diagnostics tools without radiation. Such contamination is less concerning, as it is likely to increase innovation in alternative technologies that would make our estimate more conservative.

To further mitigate potential supply-side and demand-side spillovers, the last three columns of Table 3 replicate the first three columns but use patent subclasses related to medical implants—CPC subsection 'A61F'—as the control group. 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.[13] The difference in the magnitudes between our baseline estimate and the smallest coefficient of Table 3 (column 6) provides an upper bound for the shift in patenting from RMTs to non-RMTs in radiation diagnostic technologies; this suggests that such substitution may account for, at most, 31 percent of the total effect estimated in the baseline.

[12] The estimate becomes noisier in column 3, probably because removing common patentees (which are mostly large firms that develop a wide range of imaging products) results in a lower number of patents in an (already) small number of RMT subclasses.

[13] Unreported results on the matched control group using medical implants, as well as changing the control group to include surgical instruments, also show consistent results.

6.3 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.[14] In fact, a vast majority of patents (90 percent) in radiation diagnostic devices (A61B6) applied between 2005 and 2015 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 became 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 2005-09, about nine percent of the patents in A61B6 listed an RMT subclass as a secondary classification (but not as the primary classification), whereas 19 percent did so between 2010 and 2015. Furthermore, the unique number of primary subclasses for which an RMT subclass was listed as a secondary classification by at least one patent increased from 52 to 93, suggesting that risk mitigation had become a more prevalent feature across different types of radiation diagnostic devices.

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

$$SecondaryRMT_{itcj} = Year_t + \beta NSecond_{itcj} + \gamma NClaims_{itcj} + \kappa_c + f_j + \varepsilon_{itcj},$$

where $SecondaryRMT_{itcj}$ 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 for secondary classification. The dummies $Year_t$ 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, $NSecond_{itcj}$, which is important because the propensity to have an RMT subclass as the secondary classification mechanically increases with the number of secondary subclasses. The regressions also include the number of claims in the patent, $NClaims_{itcj}$; primary subclasses effects, κ_c; and patent

[14] The 'Manual of patent examiner procedure' (Chapter 9/Section 903) describes how the USPTO assigns each patent to a primary class and multiple secondary subclasses.

owner (assignee) effects, f_j.

Column 1 of Table 4 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 assignee 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 were substantially more likely to include risk-mitigating features in the invention.[15]

Overall, results in this section provide further support for the idea that RMTs became a more prominent goal of research activities after the over-radiation shock.

6.4 Analysis of FDA pre-market notifications

In this section, we present difference-in-differences estimates on new product introductions using the FDA data. The dependent variable in column 1 of Table 5 is the number of 510k applications in a given product code-year. As explained previously, 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 in treated product codes 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.[16]

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 devices emitting high levels of radiation from the treatment group, whereas column 3 excludes devices emitting low levels of radiation.[17] Though not statistically different from each other, the difference-in-differences

[15] As a robustness test, we replicated the regression in column 3 in a smaller sample of patents with at least one reference to the class A61B6/032 "Transmission computed tomography [CT]". The estimates (unreported) are qualitatively and quantitatively similar to those obtained for the full sample.

[16] The pre-2010 difference in the average number of applications between treatment and control product codes is 2.52, and the actual number of applications in the control group is 1.74 after 2010, leading to a hypothetical number of applications for the treatment group after 2010 to be 4.26.

[17] To distinguish between devices with high or low radiation levels, we follow the FDA 2010 White Paper that lists computed tomography (CT), fluoroscopy, and nuclear medicine imaging exams (such as a positron emission tomography

coefficient in column 3 (i.e., treatment group containing only devices emitting high levels of radiation) is substantially greater in magnitude and more statistically significant than that in column 2. This is consistent with the idea that the increase in applications documented in column 1 was driven mostly by devices more affected by the over-radiation shock.

To provide additional evidence that the increase in applications for the treatment group was, indeed, linked to the over-radiation shock, we further identify applications that emphasize radiation 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 a 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 included this keyword. The regression in column 4 counts only the number of applications in a treated product code that did not mention 'dose' in their summary files, and column 5 counts only applications that did; and the dependent variable of the control group is the same as in 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 and radiation control.

As in the patent analysis, the 2010 shock may also have affected some of our control devices. Column 6, building on the specification in column 5, further excludes from the control group non-ionizing radiology diagnostic devices that may have experienced potential demand substitution. 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 number of applications with ionizing radiation including safety features began to increase after 2010, with an increasing magnitude over time. Appendix Table A3 confirms the robustness of our findings in this section to a number of alternative specifications.[18]

(PET) scan) as imaging procedures with relatively high radiation levels, versus other radiation-emitting procedures such as standard X-rays. We link product codes to procedures using the regulation numbers available on the FDA website. There are 669 applications in seven unique product codes linked to high levels of radiation.

[18] These include: (i) using the 2005-15 sample period, which is equivalent to that used in our patent analysis; (ii) dropping product codes with no applications during our sample period; and (iii) alternative econometric models—using

Overall, our analysis of the FDA data shows an increase in the number of new products after 2010 for diagnostic devices emitting ionizing radiation. Additional evidence suggests that this increase was 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 response in the short run was likely to have been 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 8, we provide a more-detailed description of RMTs in the case of CT scanners that is consistent with this interpretation.

7 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—we not only observe an increase in the development of RMTs but also more patenting and more new product introductions overall for radiation diagnostic devices. In principle, innovation may have increased for a number of reasons. In this paper, we highlight one particular channel: an increase in the perceived risk of the product that affects its demand. In section 4, we discuss a variety of evidence from survey studies and industry sources suggesting a significant increase in users' (physicians, radiologists, and patients) risk perception after the over-radiation shock. In this section, we provide more direct evidence for this mechanism by unbundling the shock's impact on demand. In particular, we show that after 2010, at the intensive margin, there was a large decline in the number of high-radiation imaging services performed; at the extensive margin, however, hospitals and clinics appeared to exhibit a greater propensity to upgrade equipment emitting relatively high levels of radiation. As we discuss at the end of this section, these demand changes, together with what we observe in the innovation responses, are hard to reconcile with alternative explanations.

7.1 Equipment use

To the best of our knowledge, comprehensive datasets on the usage of diagnostic imaging services are not available. Our main analysis uses data provided by Medicare, a federal health insurance program

the logarithm of (one plus) the number of applications as the dependent variable or a Poisson model.

covering people who are 65 or older. We cross-validate our result with an alternative dataset provided by the Organization for Economic Co-operation and Development (OECD).

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). Between 2005 and 2017, 572 unique CPT codes that pertain to diagnostic radiology were recorded in the Medicare data. Using the descriptions of each CPT code licensed from the American Medical Association (AMA), we categorize 507 codes into seven technology types, such as CT and MRI. This covers 95.2 percent of the total number of services rendered in 2005-2017.[19] To construct a balanced panel, we keep codes that are present throughout the 13 years, which leaves 340 codes corresponding to 76 percent of the total number of services. The final balanced panel dataset includes 4,420 year-procedure observations.[20]

Table 6 presents the difference-in-differences coefficients for the logarithm of the number of services provided, controlling for CPT and year fixed effects. Column 1 compares high-radiation procedures (including CT, PET/CT, and fluoroscopy) to low-radiation standard X-rays; and column 2 replicates the first column but uses non-radiation procedures—MRI and ultrasound—as the control group. The results show that, relative to low-radiation procedures and procedures that do not use radiation, the number of services in high-radiation procedures dropped significantly after 2010 (by about 20 percent). Columns 3 and 4 replicate the first two columns but use only control procedures that match treated, high-radiation procedures in terms of pre-trends. These produce estimates that are qualitatively similar

[19] We define the number of services of a given procedure as the sum of the number of services with the modifier 'TC' (technical component) and the modifier 'GlOBL' (including professional and technical components). We do not include the number of services coded only as the professional component because it refers to services such as readings and interpretation of a given CT exam (e.g., if the exam is performed at a separate clinic and requires second-opinion readings).

[20] This sample excludes CT procedures related to three body areas—abdomen, pelvis, and chest—for the following reasons. First, in 2011 and 2012, the AMA combined two sets of CT codes related to abdomen and pelvis into one. This is a pure coding change and is not related to any technological changes. Because these two sets of CT exams are often done together, the health literature suggests multiplying the number in the combined code by two to obtain the actual number of services conducted (Horný, et al., 2015). Second, the AMA also created a set of new codes in 2011 related to heart. These additions are likely due to new clinical applications but may substitute for some of the regular chest CT scans. To be conservative, we exclude all CT procedures related to these three body areas in the main analysis. Adding them back into the sample provides qualitatively similar results. We do not observe such changes in other technology types. It is also worthwhile noting that any substitution due to addition of new codes in the control procedures will also make the following result of a decline in the use of CT and high-radiation procedures more conservative.

to using unmatched controls.

Based on the sample used in column 4, Appendix Figure A2 plots the year-specific effect of the over-dose 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 and 2011 (p-value is 0.115), and a large decline starting in 2012 that had yet to recover as of 2017.

We cross-validate the above result with the OECD data. The downside of these data is that they are extrapolated from surveys covering only about 200 sites. On the positive side, the data include services for patients of all ages, unlike the Medicare data, which cover only the elderly. The raw data (Appendix Figure A3) paint a picture similar to our findings in the Medicare sample—relative to MRIs' increasing trend throughout our sample period, CT broke the increasing trend in 2012 and declined afterwards. Relative to the peak in 2011, the average number of CT exams between 2012 and 2017 represents a ten-percent reduction, a likely underestimation because it does not take into account the hypothetical continuation of the increasing trend in the absence of the over-radiation shock.

Overall, results in this section show a relative decline in the use of high-radiation procedures after the over-radiation shock. The medical literature also suggests that fear of radiation was an important factor behind the slower growth of CT use (Lee and Levy, 2012; Levin et al., 2012). Potentially, the decline in high-radiation procedures could have been driven by drops in Medicare payments. To address this concern, we run a series of difference-in-differences regressions on the average payment for high-radiation procedures relative to low-radiation or non-radiation procedures. We do not find any differential drops in the payment for high-radiation procedures after 2010. For example, relative to MRI and ultrasound, payments for high-radiation procedures actually increased by nine dollars after 2010, though the difference is not statistically significant.[21]

7.2 Equipment upgrade

The key data source used in the analysis of equipment upgrade and replacement is the X-ray assembler dataset provided by the FDA. Manufacturers of diagnostic X-ray systems are required to file reports of

[21] Reimbursement reductions took place with the passage of the Deficit Reduction Act, but the Act was not specifically targeted at procedures using radiation. Furthermore, this policy was enacted in 2005, a timing inconsistent with the effects described in Figure A2.

assembly upon installation of a certifiable system or component(s). The data provide information on the location of the site, the intended use (e.g., CT whole body scan, mammography, chest, and urology), and 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 gap 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 were less affected by the shock.[22] Another limitation of the data is that, for confidentiality reasons, they do not contain information on whether the report is for a new system or the replacement of a component in an existing system. The data also lack identifying information for the manufacturers and the model. To address these issues, we exploit the available information on installed components to identify reports that are likely to capture the installation of new CT systems or substantial upgrades of existing CT systems. Specifically, we identify reports for which the intended use of the components is "CT whole body scanner" and for which the installation involves at least three 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 X-ray and dental X-ray systems. The final sample is based on 6,161 CT assembly reports and 4,389 chest X-ray and 2,246 dental X-ray 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-equipment type-year.[23] Appendix Figure A4 plots the number of assembly reports for CT, dental X-ray, and chest X-ray systems over time. The CT and chest X-ray series appear to have very similar trends up to 2012, but the frequency of new CT systems increases substantially in the last few years of our sample. We observe a similar pattern comparing the number of new CT and dental X-ray systems.

Using a regression framework, column 1 of Table 7 contrasts the number of assembly reports on

[22] According to a 2012 FDA report (FDA, 2012), the radiation exposure from a CT scan is 100 to 800 times more than that from a chest X-ray. In turn, a dental X-ray involves about a quarter to half of the radiation from a chest X-ray

[23] Sites (hospitals or clinics) are defined as unique combinations of firm name, city and state in which the equipment is installed.

CT systems versus chest X-ray systems, controlling for year and site-equipment type fixed effects. The result shows that, within a site, the propensity to replace or upgrade a CT system after 2010 exceeds that for a chest X-ray system; and the magnitude of the difference-in-differences coefficient is equivalent to a 25-percent difference. Column 2 shows a similar result contrasting CT systems with dental X-ray systems. Columns 3 and 4 confirm these findings with linear probability models, in which the dependent variable is a dummy that equals one if the location has at least one assembly report for the specific equipment type.

Appendix Table A4 provides a number of robustness checks for these findings. Column 1 contrasts the number of assembly reports for CT and chest X-ray systems, controlling for the number of assembly reports for dental X-ray systems in the site. This additional variable partially controls for site-specific shocks affecting the demand for various types of devices. Column 2 performs a similar exercise contrasting new CT and dental X-ray systems, controlling for the number of new chest X-ray systems. Columns 3-6 provide robustness checks using smaller samples of larger sites.[24]

In principle, the higher propensity to upgrade CT scanners could have been a result of lower prices charged by CT producers. Historical prices for CT prices turn out to be very difficult to obtain. The only information we are able to obtain is from the 2014 IBIS Procurement Report, which estimates that the benchmark price of CT scanners had been rising monotonically between 2005 and 2014.[25] Even though we cannot completely rule it out, the available price information is not consistent with this explanation. Moreover, it is important to note that we have encountered no mentions of this factor in industry accounts around the time or in the interviews we have conducted.

It is also possible that the higher propensity to upgrade CT scanners is partially explained by regulatory pressures. As discussed previously, involvement of regulators and the potential 'demand-forcing' effect of new industry standards are inherently important for safety-related innovations. It is challenging to precisely differentiate hospitals' genuine demand for safer machines from extra regulatory requirements beyond that. That said, qualitative evidence from the industry suggests that demand for

[24] Columns 3 and 4 replicate the analysis using sites with at least one assembly report for one of our three procedures (7,292 sites). Columns 5 and 6 focus on the 2,988 sites with at least four assembly reports (top three percent of our sample).

[25] "IBISWorld Procurement Report: 30105050 CT Scanners," by Keiko Cadby, July 2014, IBIS World.

safer CT scanners by physicians and hospitals, rather than pure regulatory pressure, is likely to be a key channel behind the equipment upgrade. For example, following the over-radiation shock, the American Association of Physicists in Medicine and the American Society of Radiation Oncology released a series of recommendations that included a request to vendors to incorporate warning systems to alert operators to unusual features of the scans or possible malfunctions of the devices (Hendee and Heman, 2011). Similarly, the American College of Radiology mandated annual CT protocol reviews as part of its CT accreditation program. Such reviews required each facility to set up a team to critically evaluate the safety of available scanner technologies and to consider new machines introducing safety features (Kofler et al., 2014).[26]

7.3 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 experienced a large and sustained decline relative to non-radiation technologies; (ii) firms increased innovation aimed at mitigating radiation risk; and (iii) hospitals and clinics increased their propensity to upgrade and replace their CT systems.

In isolation, the changes at the intensive and the extensive margin of demand may be explained by a number of demand or supply shifters. For example, the drop in equipment use may be explained by a decline in the overall demand for imaging services or a technological breakthrough in alternative technologies. On the other hand, a higher propensity to upgrade equipment can potentially be explained by an increase in the demand for superior image quality, by lower production costs, or by positive financial shocks affecting the hospitals. Each of these alternative explanations, however, cannot easily explain the joint presence of all the above patterns—changes at the two margins of demand, as well as the increase in RMT-related innovations. The overall evidence suggests that the increase in risk perception, as corroborated by the anecdotal and survey evidence discussed in section 4, is likely to

[26] Evidence for hospitals' greater demand for safer machines is also present in a number of industry publications. For instance, in a 2016 interview with Diagnostic and Interventional Cardiology magazine, Leslee Shaw, the co-director of the Emory Clinical Cardiovascular Research Institute, stated that "*There is a lot of concern today about the overuse of CT and overexposure of patients to radiation. So, having as a marketing piece that you are very concerned about patient-centered imaging and safety, and that you are using new technology to decrease dose—that is something you can make a great business case for. Or, to tell people that you are updating your technology to look precisely for improved patient care.*" Source: https://www.dicardiology.com/article/what-consider-when-buying-new-ct-scanner.

have been a key driver of the data patterns we observe.

As discussed in section 3, the overall effect of risk perception on demand is potentially ambiguous. In our empirical setting, the positive effect on the demand at the extensive margin may have turned the negative information shocks into opportunities for CT producers. One potential explanation for this result is that imaging equipment such as CT scanners are durable goods, and, in the short run, hospitals and clinics could easily consolidate use and reduce the demand for the number of machines. The impact of risk perception on demand and, hence, innovation incentives, may be different in markets in which usage can be easily consolidated or for consumable, rather than durable, goods. Our analysis, thus, indicates that the link between risk perception and innovation depends on factors such as the nature of the product and market structure.

Assessing the welfare impact of reduced CT use is beyond the scope of this paper. On the one hand, it is possible that this reduction may have led to under-diagnosis of patients. On the other hand, if the claim quoted by Brenner and Hall (2007) that roughly 30 percent of CT procedures are not necessary is, indeed, true, it is possible that the reduction was due mostly to noncritical use. Then, the over-radiation shock may have provided some sort of realignment 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' cumulative radiation exposure and partly due to liability concerns about misuse).[27]

Finally, despite the innovation responses, the use of CT did not quite recover relative to non-radiation technologies as of the end 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 payment or find ways to consolidate the number of machines to be purchased. These long-run

[27] Potential reasons for over-testing may include financial motives or fear of medical malpractice liability, which could result from potential allegations of not doing enough (often labeled as 'defensive medicine'). Assessing the interplay between these various incentives, as well as the possible welfare costs of under-diagnosing, is potentially interesting for future research.

responses by the hospitals may, in turn, further influence firms' innovation activities.

8 Characterizing RMTs: the case of CT scanners

In section 6 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. Our analysis 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 that rely on fundamentally different scientific principles and represent a substantial change in the technological path. Many of the first type of changes followed recommendations by the regulator and were implemented through a series of new standards set by the industry. The second type of changes, however, went substantially beyond the level requested by the regulator; this reflects the notion that market demand for safer machines played an important role in shaping the direction of technological progress and led to a new dimension in which firms could innovate and compete. The second type of RMTs also relates to important concepts proposed by the literature, including the distinction between technological paradigms and trajectories (Dosi, 1982); dominant designs (Utterback and Abernathy, 1975); and technological discontinuities (Anderson and Tushman, 1990).

8.1 Progress along the existing, dominant technological path

One type of RMTs developed by CT scanner producers appeared to tackle 'low-hanging fruit,' in the sense that the goal of the improvement was to prevent radiation overdose or to manage dosage more efficiently. These innovations, though important and likely to make a meaningful difference, did not require substantial R&D investment or substantial departure from existing technologies. 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.[28]

A natural question is why these safety checks were not incorporated 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 workflow. Furthermore, what reference values to set and who sets them may have implications for the allocation of liability in the case of negative events.[29]

8.2 Change in the technological path

The second type of RMTs differs qualitatively from what we described in the previous section: it involves a substantial departure from the existing technological path 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. This method underlies the strong dependency of image quality on radiation dose. After the over-radiation shock, CT manufacturers as a whole significantly accelerated the development of a methodology that breaks this dependency and, as GE Healthcare put it, "establishes new rules in the relationship between image quality and dose reduction."[30]

For over 30 years, the dominant method of image reconstruction had been filtered back projection

[28] 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.

[29] These concerns may be reflected in how the standards evolved 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 manufacturers pre-populated the dose check alert and notification values.

[30] "Introducing Veo on Discovery CT750 HD," GE Healthcare White Paper, 2011.

(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 dosage used, which, therefore, 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 improves 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 1970s. The reason that FBP, instead, became the dominant method is 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.[31]

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 below, about half of the CT systems introduced after 2010 included an IR option.

It is important to note that IR algorithms involve 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 that of FBP. For example, in 2014 the typical speed for FBP was 2.9-6.6 images per second, whereas the IR speed was 0.2-0.5 images per second (Ginat and Gupta, 2014; Geyer et al., 2015). Such a long reconstruction time (ranging between ten 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 make the images difficult to interpret and require retraining of radiologists (Raman et al., 2013; Ramirez-Ghiraldo et al., 2018). In the few years after the shock, we witnessed three generations of IR algorithms, each improving upon the previous one in

[31] Dave Fornell, "Iterative Reconstruction 101," Imaging Technology News, July 23, 2013, https://www.itnonline.com/article/iterative-reconstruction-101-0, accessed January 23, 2019.

speed or other aspects of image quality, including mimicking the image texture of a full-dose FBP image to make it easier for radiologists to read the images and different options intended to strike a balance between speed and the level of dose reduction.[32]

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 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 driven purely by regulatory interventions, rather than by a shift in demand and consumer preferences.

8.3 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.[33] 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

[32] Source: "Iterative Reconstruction in CT: What Does It Do? How Can I Use It?" by William P. Shuman, November 2010, Image Wisely, American College of Radiology. Source: https://www.imagewisely.org/Imaging-Modalities/Computed-Tomography/Iterative-Reconstruction-in-CT.

[33] In particular, we define a feature as 'dose reduction' if the word 'dose' is used in conjunction with keywords including 'reduction,' 'lower,' 'reduced,' 'less,' and 'little." The remaining incidences are defined as 'dose efficiency/check.' Keywords used include 'optimization,' 'efficiency,' 'check,' 'verification,' 'notify,' 'alert,' etc.

features. The figures show that both types of safety features were rarely mentioned in the application summary files before 2010, whereas they were increasingly more likely to appear afterwards. Between 2014 and 2017, for example, 37.5 percent of all applications mentioned dose check or efficiency, and 25 percent mentioned 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 included an IR option, and 20 percent of the software packages were specifically related to this method. Moreover, the data show that all 118 applications after 2010 without an IR option failed to mention dose reduction, whereas 38 out of 66 applications (58 percent) that included an IR option did mention the term. This contrast is consistent with our understanding that substantial dose reduction is achievable only with the IR methodology.

9 The role of large incumbents

In this section, we examine the extent to which the increase in RMT innovation— at both the invention and commercialization stages—is driven by large incumbent 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, including smaller incumbents, new entrants, individual inventors, and research entities. The top five firms are Toshiba, Siemens, Hitachi, GE, and Philips. These firms had the highest numbers 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 difference-in-differences 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 was driven by the top five firms,

while the smaller patentees drove the rest. 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 of the two coefficients. Relative to the patenting rates in RMT subclasses before 2010, the increase in patenting was 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 was 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 were 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 were economically substantial for both the largest firms and smaller patentees; and (ii) relative to the patenting stage, the largest firms seem to have played a more prominent role than 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 industry.

First, as discussed previously, information shock on product safety is likely to exhibit externalities and to affect the entire product category—in particular, the demand of mainstream customers served by large incumbents. In other words, conditions often characterized in theories such as disruptive innovation—that is, the innovation is initially not valued by mainstream customers—are not satisfied in our context (Christensen and Bower, 1996). Second, the types of RMTs described in section 8 do not fit 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).

10 Conclusions

In this paper, we examine the impact of risk perception on innovation, taking advantage of the disclosure and the extensive reporting of a set of unexpected CT scan over-radiation accidents in late 2009.

Our results show significantly increased patenting of features of radiation diagnostic devices that mitigate radiation risk, relative to patenting of other features—on the order of 110 percent. Using FDA data, we also find a significant increase in the number of new products for diagnostic devices emitting ionizing radiation relative to control devices that do not use radiation, and this increase is driven by products for which radiation control features are prominent. For the underlying mechanisms, we provide survey, interview, and other qualitative evidence suggesting that risk perception by the users (physicians, radiologists, and patients) changed substantially after the over-radiation shock. Quantitatively, we find that the shock led to (i) fewer high-radiation diagnostic procedures performed (i.e., a decrease at the intensive margin); and (ii) a greater propensity to upgrade CT scanners (i.e., an increase at the extensive margin). These demand-side results are consistent with the idea that changes in risk perception played an important role in driving firms' innovation investments. Focusing on CT scanners, we further document two different types of RMTs, encompassing both minor improvement of existing technologies and a substantial redirection of the technological path.

Ultimately, our paper suggests that changes in risk perception can be an important driver of innovation and shape the direction of technological progress. Increased risk perception, in principle, has ambiguous effects on the demand for a product. In settings such as ours—products are durable goods, and it is costly for users to consolidate use or to find substitute products—the positive effect of a higher willingness to pay for safety may dominate the chilling effect on innovation. Finally, large players may play an important role in the development and, even more so, in the commercialization of risk-mitigating technologies, and this has important implications for the dynamics of competitive advantage and market structure.

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Data appendix

Risk mitigating technology subclasses

The following lists the subclasses that we manually classify as Risk Mitigating Technology subclasses:

A61B 6/10 "Application or adaptation of safety means"

A61B 6/107 "Protection against radiation, e.g. shielding (techniques for handling radiation not otherwise provided for G21K"

A61B 6/54 "Control of devices for radiation diagnosis"

A61B 6/542 "involving control of exposure"

A61B 6/544 "dependent on patient size"

A61B 6/545 "involving automatic set-up of acquisition parameters"

A61B 6/58 "Testing, adjusting or calibrating devices for radiation diagnosis"

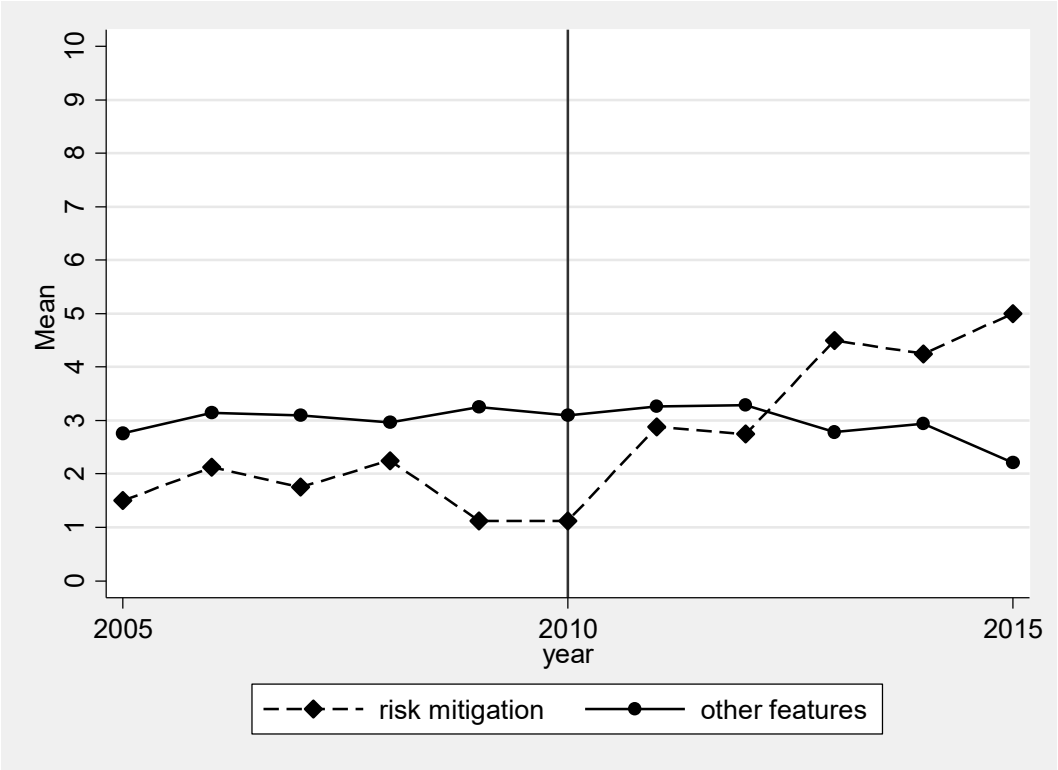
A61B 6/586 "Detection of faults or malfunction of the device".

Theses subclasses were chosen exploiting a two-stage process. First, reading the description of the subclasses from the USPTO web-site, we identified subclasses A61B6/107, A61B6/542, A61B6/544, A61B6/545 and A61B6/586 as subclasses including risk mitigating technologies. Second, for each of these subclasses, we also included their related higher-level 'parent' subclasses. This is because a parent subclass contains residual patents that cannot be easily categorized into a specific children subclass and, therefore, may include broader patents that involve features of various lower level children subclasses.

Keyword analysis

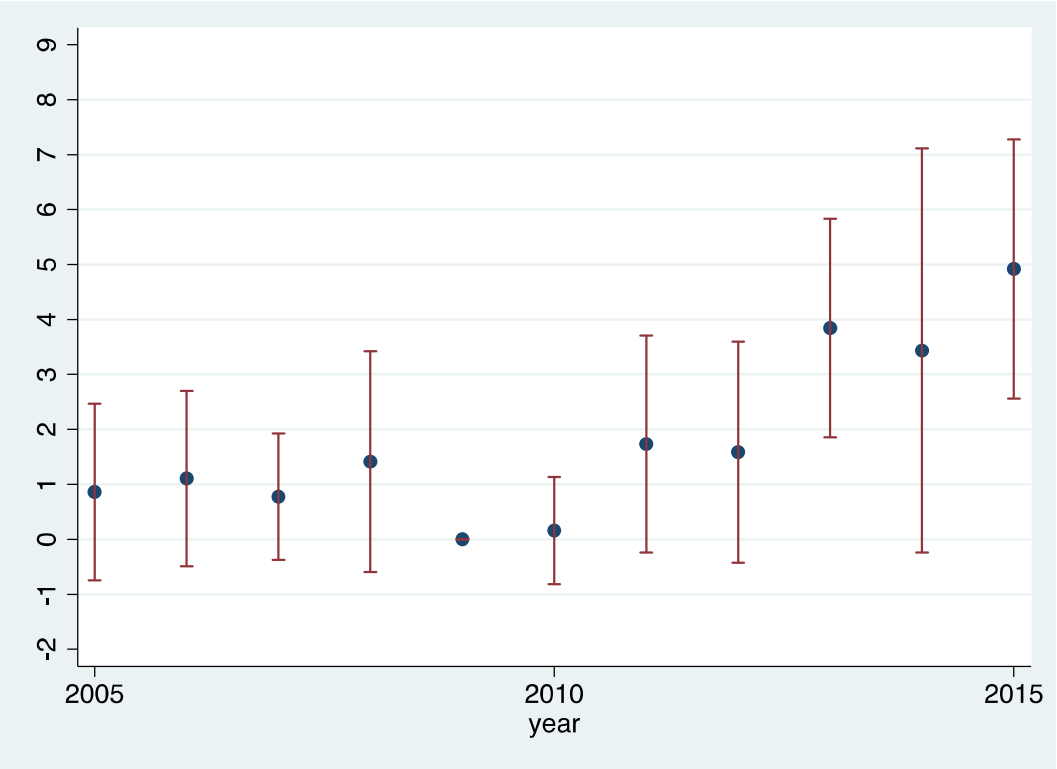
The keywords in the dictionary are: "safety monitor" "radiation shield" "radiation blocking" "dose control" "reducing electromagnetic radiation" "reducing radiation" "dose modulation" "exposure control" "radiation protection" "low-dose" "x-ray intensity" "radiation exposure" "x-ray exposure" "x-ray dose" "radiation attenuation" "x-ray emissions" "dose rate control" "radiation dose" "radiation minimization" "x-ray irradiation" "dosage detection" "x-ray emission" "radiation shielding" "radiation protection" "dose distribution" "x-ray exposure" "dose information" "x-ray reduction".

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



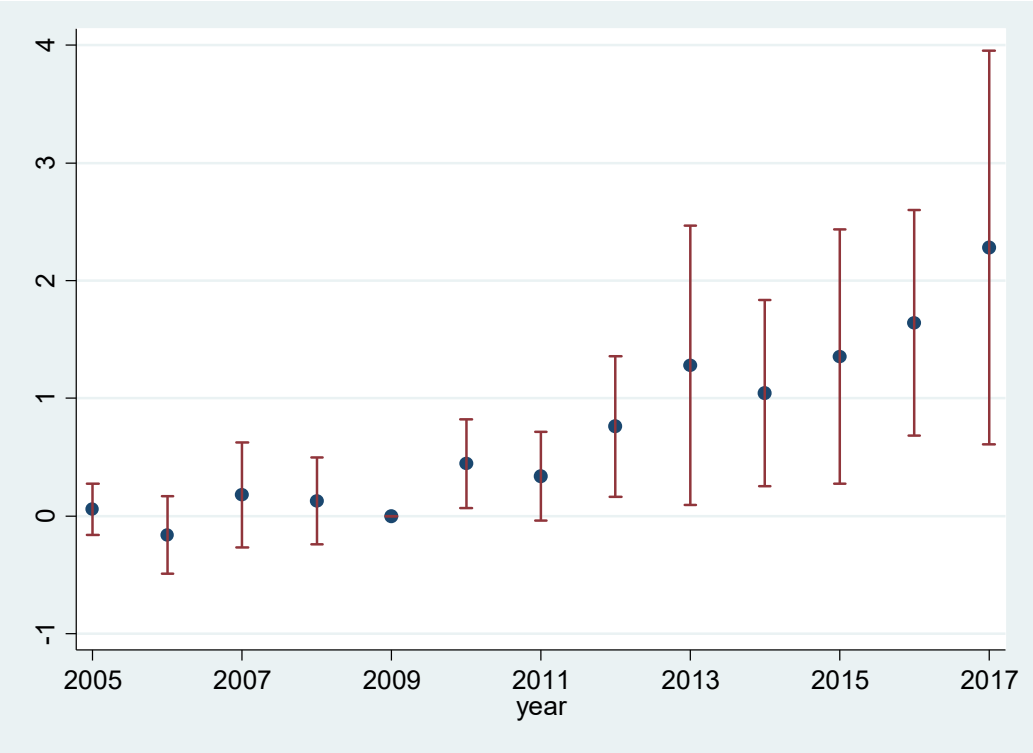
Notes: raw data. Average number of patents in risk-mitigating technology subclasses versus other subclasses in radiation diagnostic devices (i.e., CPC group A61B6).

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 (i.e., 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

	Obs.	Mean	Std. Dev.	Min	Max
Patent applications					
Patents	1540	2.962	6.185	0	97
Year	1540	2010	3.163	2005	2015
Risk-Mitigating Technology Subclass	1540	0.057	0.232	0	1
FDA applications					
Applications	19474	1.819	5.327	0	110
Year	19474	2011	3.742	2005	2017
Ionizing Diagnostic Radiology Codes	19474	0.013	0.112	0	1

Notes: 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 a product code-year. Ionizing Diagnostic Radiology Codes = 1 for product codes related to radiology diagnostic devices emitting ionizing radiation.

Table 2. Patenting response to the over-radiation shock

	(1)	(2)	(3)	(4)
Dependent variable	Patents	Patents	Patents	Patents
RMT x After 2010	1.783**	1.785**	2.650**	0.727*
	(0.809)	(0.814)	(1.166)	(0.402)
Year effects	YES	YES	YES	YES
Subclass effects	YES	YES	YES	YES
Note	Baseline	Drop if all zeros	Start at first patent	Only CT patents
Observations	1540	1507	1001	1540

Notes: 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. RMT = 1 for patent subclasses involving risk-mitigating technologies. Column 2 drops subclasses with zero patents during the entire sample period; column 3 uses an unbalanced panel that includes only observations for which we observe at least one patent in this particular subclass in previous years; and column 4 uses only CT patents (that is, those referring to subclass A61B6/032 as either primary or secondary classification).

Table 3. Alternative control groups for the patent analysis

	(1)	(2)	(3)	(4)	(5)	(6)
Dependent variable	Patents	Patents	Patents	Patents	Patents	Patents
RMTX After 2010	1.522**	1.690**	1.544*	1.229*	1.424**	1.224**
	(0.719)	(0.719)	(0.963)	(0.720)	(0.720)	(0.492)
Control Group	A61B5 and A61B8	A61B5 and A61B8	A61B5 and A61B8	A61F	A61F	A61F
Drop overlapping patentees	NO	from control	from treatment and control	NO	from control	from treatment and control
Year effects	YES	YES	YES	YES	YES	YES
Subclass effects	YES	YES	YES	YES	YES	YES
Observations	7744	7744	7744	8767	8767	8767

Notes: 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. The control group used in columns 1-3 includes diagnostic medical devices that do not use radiation or ultrasound (A61B5) and diagnostic devices that use ultrasound (A61B8). The control group used in columns 4-6 includes medical implant patents (A61F).

Table 4. Effects of the over-radiation shock using secondary patent classification

	(1)	(2)	(3)
Dependent variable	at least one RMT secondary subclass	at least one RMT secondary subclass	at least one RMT secondary subclass
Year 2005	-0.014	-0.008	0.021
	(0.020)	(0.021)	(0.034)
Year 2006	-0.007	0.003	-0.001
	(0.020)	(0.020)	(0.031)
Year 2007	-0.018	-0.004	0.015
	(0.020)	(0.020)	(0.030)
Year 2008	-0.021	-0.017	-0.028
	(0.020)	(0.020)	(0.030)
Year 2010	0.031	0.040*	0.044
	(0.023)	(0.023)	(0.033)
Year 2011	0.058**	0.063***	0.063*
	(0.023)	(0.024)	(0.036)
Year 2012	0.085***	0.094***	0.097***
	(0.024)	(0.024)	(0.037)
Year 2013	0.090***	0.111***	0.100**
	(0.027)	(0.027)	(0.040)
Year 2014	0.120***	0.143***	0.126***
	(0.027)	(0.027)	(0.043)
Year 2015	0.059*	0.075**	0.033
	(0.033)	(0.032)	(0.050)
Number of secondary subclasses	0.016***	0.017***	0.020***
	(0.002)	(0.002)	(0.003)
Number of claims	-0.001	0.001	0.001
	(0.001)	(0.001)	(0.001)
Primary subclass effects	NO	YES	YES
Assignee effects	NO	NO	YES
Observations	4,131	4,131	4,131

Notes: Patent-level linear probability regressions. Sample includes all patents in radiation diagnostic medical devices (A61B6) for which the primary subclass is not 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 5. FDA Pre-market notifications

	(1)	(2)	(3)	(4)	(5)	(6)
Dependent variable	Apps	Apps	Apps	Apps (without dose)	Apps (with dose)	Apps (with dose)
Ionizing diagnostic devices	1.250*	0.871	1.900*	0.234	1.091**	1.102**
*After 2010	(0.690)	(0.873)	(1.076)	(0.580)	(0.442)	(0.441)
Year FE	Y	Y	Y	Y	Y	Y
Product code FE	Y	Y	Y	Y	Y	Y
Control group	Non-ionizing radiology and non-radiology devices	Non-ionizing radiology and non-radiology devices	Non-ionizing radiology and non-radiology devices	Non-ionizing radiology and non-radiology devices	Non-ionizing radiology and non-radiology devices	Non-radiology devices
Treatment group	All radiation diagnostic devices in radiology	Only low-radiation diagnostic devices	Only high-radiation diagnostic devices	All radiation diagnostic devices in radiology	All radiation diagnostic devices in radiology	All radiation diagnostic devices in radiology
Observations	19474	19383	19318	19474	19474	18876

Notes: OLS regressions with 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 for ionizing diagnostic radiology product codes (i.e., the treatment group) counts only applications not containing the word 'dose' in the summary files. In columns 5 and 6, the dependent variable for ionizing diagnostic radiology product codes counts only applications containing the word 'dose' in the summary files. Ionizing diagnostic devices = 1 for product codes related to radiology devices emitting radiation.

Table 6. Equipment usage in Medicare data

	(1)	(2)	(3)	(4)
Dependent Variable	log(Services)	log(Services)	log(Services)	log(Services)
Treated procedures * After 2010	-0.214**	-0.189*	-0.224**	-0.189
	(0.096)	(0.100)	(0.106)	(0.116)
Year effects	Y	Y	Y	Y
CPT effects	Y	Y	Y	Y
Control group	low radiation	MRI and ultrasound	Matched low radiation	Matched MRI ultrasound
Observations	3042	2054	1664	1378

Notes: 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. Treated procedures are high-radiation procedures including CT, PET/CT, and fluoroscopy. Control procedures in columns 1 and 3 are standard X-ray procedures with low radiation; and control procedures in columns 2 and 4 include non-radiation procedures (that is, MRI and ultrasound).

Table 7. Equipment upgrade

	(1)	(2)	(3)	(4)
Dependent variable	Number of assembly reports	Number of assembly reports	Assembly dummy	Assembly dummy
CT Scanners X After 2010	0.004***	0.003***	0.003***	0.005***
	(0.001)	(0.001)	(0.001)	(0.001)
Control Group	Chest	Dental	Chest	Dental
Year effects	YES	YES	YES	YES
Site-equipment type effects	YES	YES	YES	YES
Observations	715330	715330	715330	715330

Notes: 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.

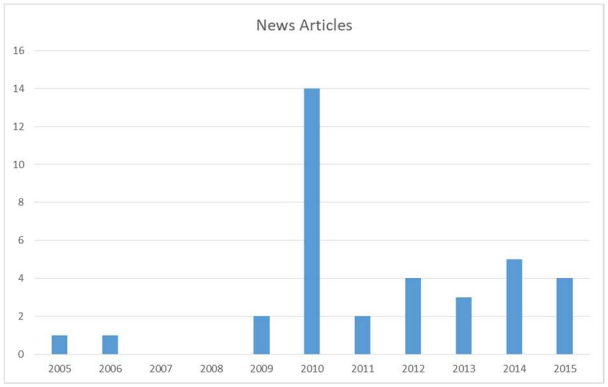
Table 8. Heterogeneous effects by firm size

	(1)	(2)	(3)	(4)
Dependent Variable	Patents by top 5 firms	Patents by other firms	FDA applications by top 5 firms	FDA applications by other firms
RMT x After 2010	0.600*	1.183		
	(0.337)	(0.722)		
Ionizing radiology device x After 2010			0.549*	0.701
			(0.329)	(0.591)
Year effects	YES	YES	YES	YES
Subclass effects	YES	YES	NO	NO
Product code effects	NO	NO	YES	YES
Observations	1540	1540	19474	19474
Baseline	0.791	0.854	1.370	2.926

Notes: OLS regressions with robust standard errors clustered at the sublcass 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.

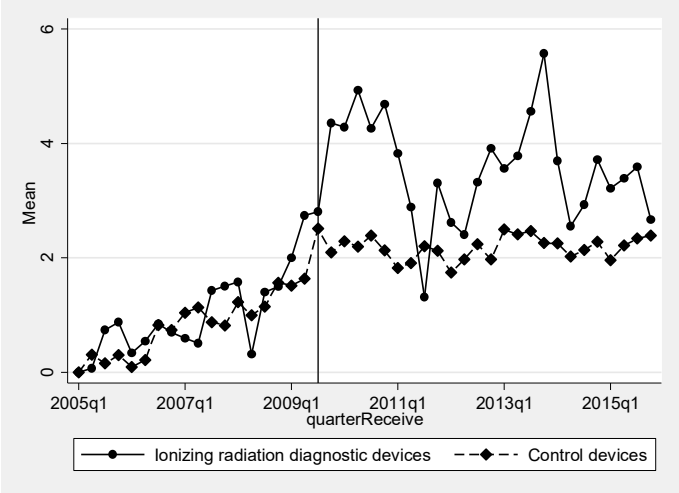
Figure A1: Timing of the over-radiation shock

a. Media mentions of CT scan and X-ray radiation



Source: Factiva (Dow Jones) textual searches uses keywords ('CT scan' or 'X-ray') and 'dose' in headline and the leading paragraph of articles published in leading media outlets.

b. FDA approval time (months)



Notes: quarterly data on the average number of months from application to approval for our treatment group (ionizing radiation diagnostic product codes) and the control group (non-radiation diagnostic product codes and non-radiology devices). For each group, we subtract the data by the average approval time in the first quarter of 2005. Thus, the two series have the same starting point at zero.

c. Google Trends of keyword "CT Scan Radiation"

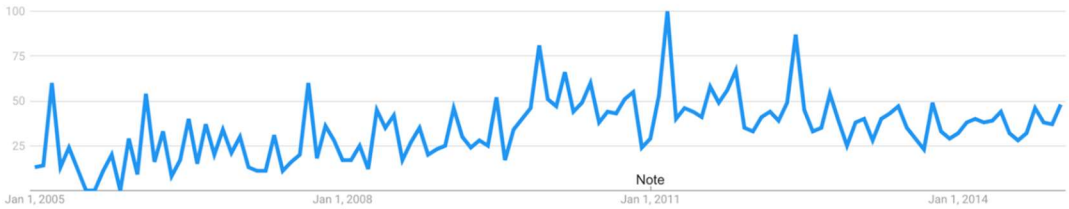
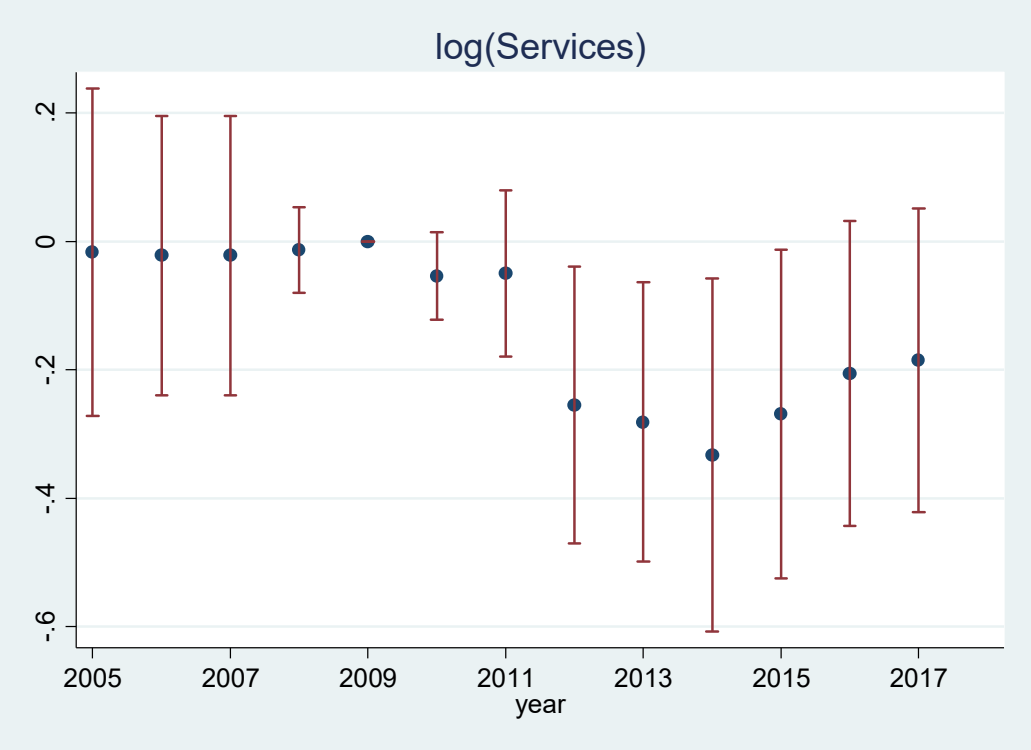
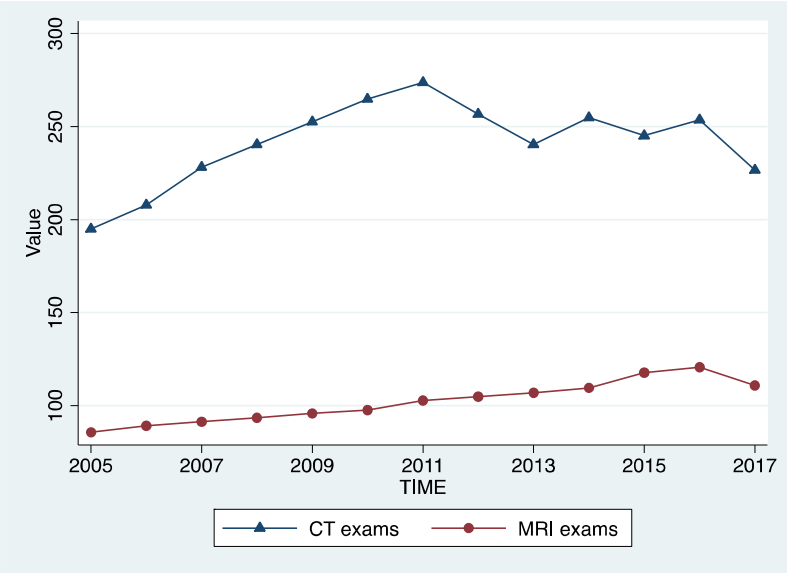


Figure A2: **Year-specific effects on the number of CT services relative to MRI and ultrasound**



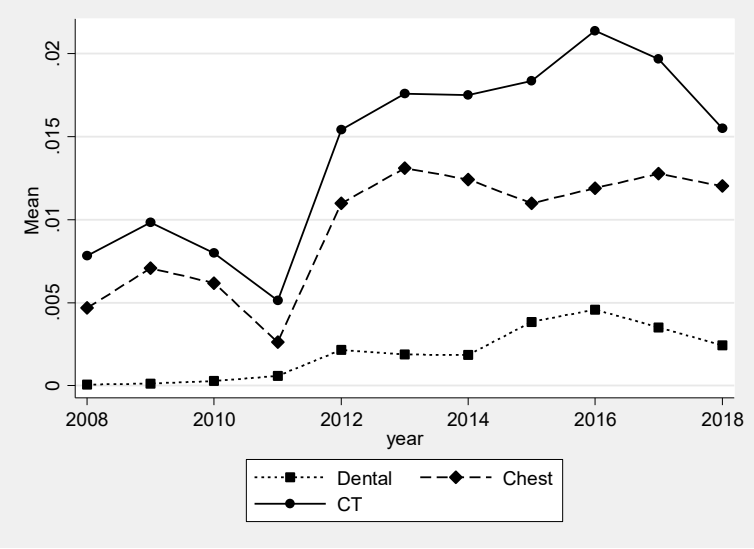
Notes: The treatment group includes Current Procedural Terminology (CPT) codes for high-radiation procedures including CT, PET/CT, and fluoroscopy; and the control group includes CPT codes for MRI and ultrasound that match to the treated CPT codes in terms of pre-trends. The dependent variable of the difference-in-differences regression is log(number of services), and the regression controls for CPT and year fixed effects.

Figure A3: Estimated numbers of CT and MRI exams per million people



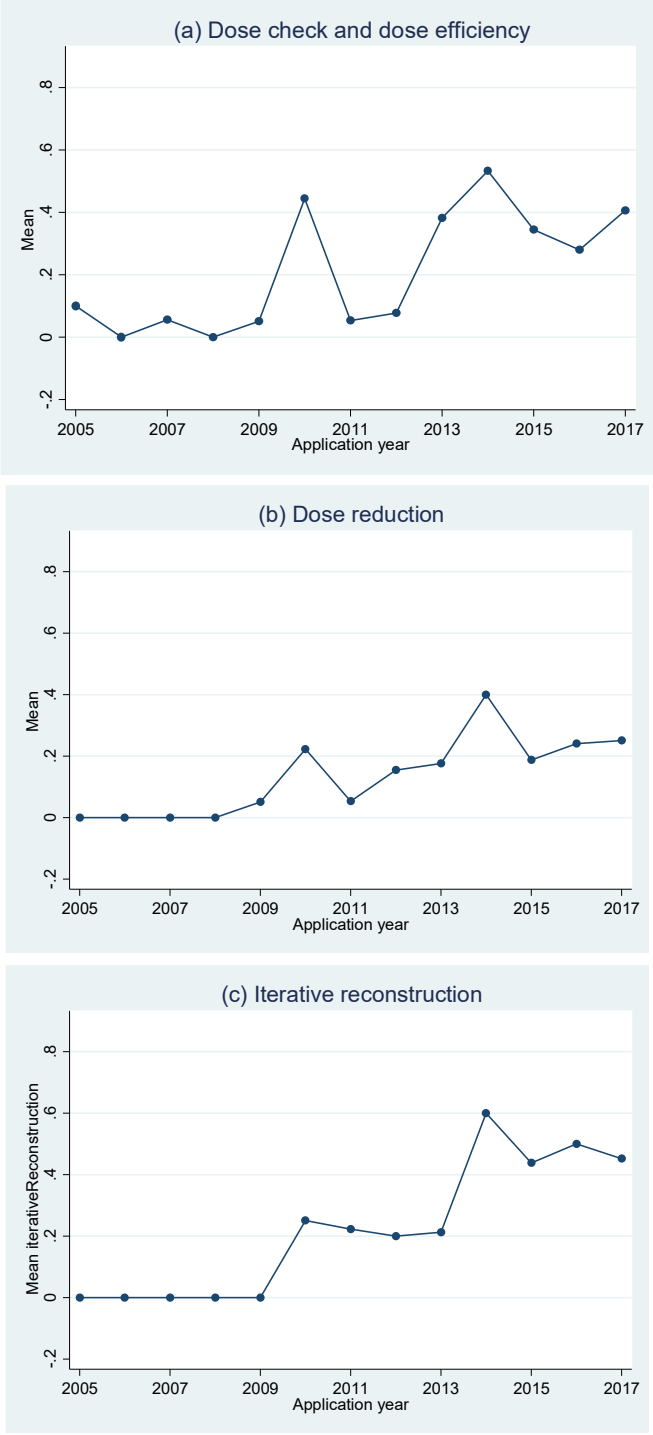
Source: https://data.oecd.org/healthcare/computed-tomography-ct-scanners.htm. The data are based on IMV benchmark reports that extrapolate data to the national level based on a survey of over 200 sites.

Figure A4: Average assembly reports for CT scanners, chest and dental X-ray equipment



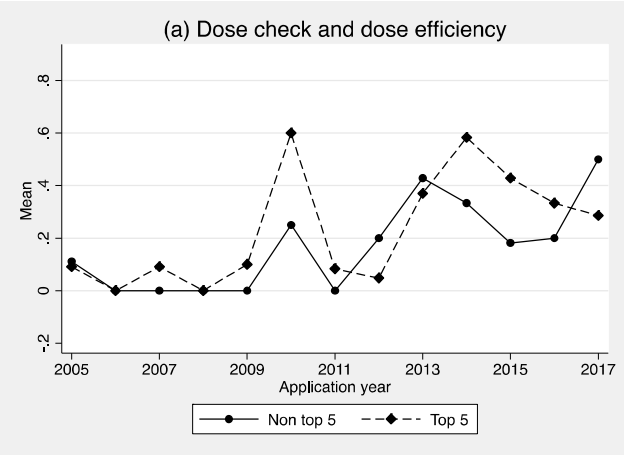
Notes: average number of assembly reports in a given site-equipment type-year. The data are based on the FDA X-ray assembler dataset.

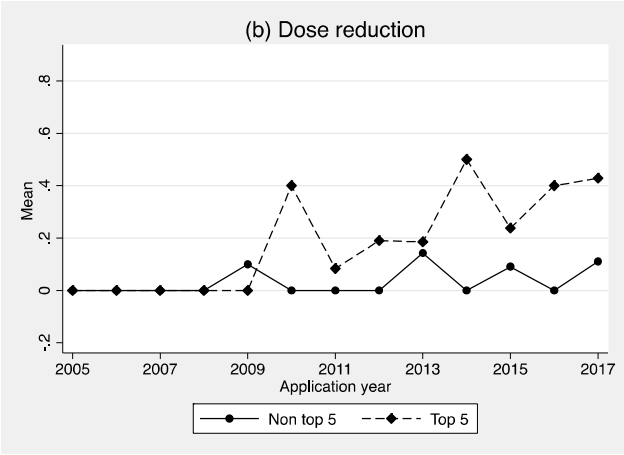
Figure A5: Risk-mitigating technologies in CT Scanners

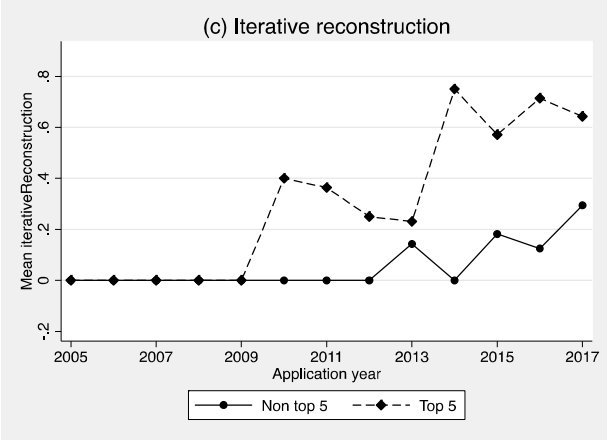


Notes: percentages of applications in a given year including a certain type of safety-related features in the summary files. The data are based on 294 510k applications in the product code JAK (CT scanners).

Figure A6: Risk-mitigating technologies in CT Scanners: top five firms versus smaller firms







Notes: percentages of applications in a given year including a certain type of safety-related features in the summary files. The data are based on 294 510k applications in the product code JAK (CT scanners).

Table A1. Patenting response to the over-radiation shock: robustness

	(1)	(2)	(3)	(4)	(5)
Dependent variable	log(Patents+1)	Patents	Patents	Patents	Patents
RMT x After 2010	0.219*	0.476**	0.708***	4.607**	1.783**
	(0.118)	(0.205)	(0.248)	(2.104)	(0.817)
Year effects	YES	YES	YES	YES	YES
Subclass effects	YES	YES	YES	YES	YES
Model	OLS	Negative binomial	Poisson	Weigthed OLS	Bootstrap
Observations	1540	1507	1507	1540	1540

Notes: 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 A2. Keyword approach to identifing RMT patent subclasses

	(1)	(2)	(2)	(3)	(4)
Dependent variable	Patents	Patents	Patents	Patents	Patents
RMT x After 2010	1.509**	1.688**	1.614**	1.845***	0.734
	(0.714)	(0.743)	(0.699)	(0.681)	(0.781)
Year effects	YES		YES	YES	YES
Subclass effects	YES		YES	YES	YES
RMT-patent fraction threshold for treatment subclasses	Top 5%	Top 5% and drop mixed classes	Top 10%	Top 15%	Top 20%
Observations	1540	1320	1540	1540	1540

Notes: 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. RMT = 1 for patent subclasses involving risk-mitigating technologies. Column 2 defines the treatment group in the same way as column 1 but drops subclasses from the control group if more than two percent of their patents are RMT patents.

Table A3. FDA Pre-market notifications: robustness

Dependent variable	(1) Apps (with dose)	(2) Apps (with dose)	(3) log[Apps (with dose)+1]	(4) Apps (with dose)
Ionizing radiology device *After 2010	0.829**	1.373**	0.145**	1.774***
	(0.368)	(0.536)	(0.072)	(0.370)
Year FE	Y	Y	Y	Y
Product code FE	Y	Y	Y	Y
Control group	Non-radiology devices	Non-radiology devices	Non-radiology devices	Non-radiology devices
Note	Only years 2005-15	Drop codes with no applications	Log dependent variable	Poisson
Observations	15972	18824	18876	18824

Notes: OLS regressions with robust standard errors clustered at the product code level. * significant at 10 percent, ** significant at 5 percent and *** significant at 1 percent. Apps (with dose) = the number of FDA applications in a product code-year, only counting 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 A4. Equipment upgrade: robustness

	(1)	(2)	(3)	(4)	(5)	(6)
Dependent variable	Assembly dummy	Assembly dummy	Assembly dummy	Assembly dummy	Assembly dummy	Assembly dummy
CT Scanners X After 2010	0.003***	0.005***	0.013***	0.024***	0.028***	0.040***
	(0.001)	(0.001)	(0.002)	(0.002)	(0.003)	(0.003)
Dental X-ray assembly reports	-0.001***					
	(0.001)					
Chest X-ray assembly reports		0.014***				
		(0.003)				
Control group	Chest X-ray	Dental X-ray	Chest X-ray	Dental X-ray	Chest X-ray	Dental X-ray
Year effects	YES	YES	YES	YES	YES	YES
Sie-equipment type effects	YES	YES	YES	YES	YES	YES
Sample	full	full	at least 1 major assembly	at least 1 major assembly	at least 4 major assemblies	at least 4 major assemblies
Observations	715330	715330	160424	160424	65736	65736

Notes: OLS regressions with robust standard errors clustered at the clinic level. * significant at 10 percent, ** significant at 5 percent and *** significant at 1 percent. Assembly dummy = 1 if at least one assembly report in equipment type-site-year. Assembly reports= the number of assembly reports related to a specific tpe of equipment in the site-year.