Assessment of medical device regulator COVID-19 policies on entry to market for prioritised devices: A case study.

Short title: Policies and medical device market entry

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Abstract

Background

In response to the COVID-19 global pandemic, the World Health Organization developed a list of devices that were deemed essential for the clinical management of COVID-19. In the UK, medical devices were given exceptional use authorisations during the pandemic. Medical device regulators around the world modified their administrative approach to medical device approval in order to ensure that relevant devices and personal protection equipment (PPE) would be available to healthcare professionals and patients. Using data from the medical device regulators in the United States and Australia, we assessed the impact of COVID-19 related regulatory modifications intended to allow for a quick market entry of relevant equipment.

Methods

The data from the regulators are treated as a case study in understanding policy changes. All COVID-19 devices and PPE were identified in the data leveraging the Global Medical Device Nomenclature and the device descriptions. A 10-day and 20-day moving average was applied to assess how many of these ended up in the market over time.

Results

In both data sets, the number of market entries increased after the start of the pandemic. However, a greater effect (in bringing the necessary devices to market) was observed for Australia when the available data was compared to the United States.

Conclusion

This study showed that in general market entry of relevant equipment increased during the pandemic, indicating a possible policy effect. Nonetheless, the kind of data captured within the national databases greatly influences the ability to accurately track performance of regulatory policy changes. This work shows the potential of using data science within a regulatory context for assessing if a policy change creates the desired effect.

Key words

Data Science, Equipment and Supplies, Informatics, Policy, MRegTech

Introduction

The severe acute repository syndrome coronavirus 2 (SARS-CoV-2 or more commonly known as, COVID-19) pandemic threatened health services around the world and disrupted the global economy. On 11 March 2020, the WHO declared COVID-19 to be a pandemic. At the end of 2021, the World Health Organization (WHO) reported that there were more than 290.6 million COVID-19 cases and over 5.4 million related deaths (World Health Organization, 2021). The ability for governments to secure sufficient amounts of personal protection equipment (such as masks, gloves, and medical gowns), as well as more sophisticated devices (e.g. ventilators) was essential early in the COVID-19 pandemic. To address any lack of supplies, governments allowed medical device regulators to modify the rules in order to bring new products faster on to the market.

The declaration of the COVID-19 pandemic led to a temporary reduction in manufacturing and supply, putting pressure on the overall supply chain (Ishida, 2020). The result was that during the pandemic parts necessary to make sophisticated equipment did not reach manufacturing plants on time, disrupting their 'just-in-time' model. The global supply chain of medical devices relies on a 'just-in-time' supply chain model, so that inventories can be kept low in order to reduce costs. The manufacturing supply chain is one of tightly organized interdependence, which is especially true for the more complex devices. In contrast, low-tech devices (for example facemasks and gloves) tend to rely more on third-party contracting. This means that low- and middle-income economies can manufacture these at relatively low cost. The supply chain relies on having low economic and political barriers, as well as a robust global transportation system and a clear regulatory framework, to bring these devices to market.

One of the results of this disruption was that simple, but critical devices like personal protection equipment (PPE) were no longer being exported from low- and middle income countries. The shortfall of PPE supplies for health care professionals led to an increase in requests for safety equipment from other industries (such as construction) in order to meet the growing need for these devices. Some health care professionals were even using unconventional equipment, such as snorkels or even rubbish bags (Livingston, Desai, and Berkwits, 2020) to act as a temporary alternative to PPE. The pressure to provide new devices prompted a growth in open-source design and manufacturing. Using 3D printing and the re-purposing of designs, new masks and ventilators were being created. However, these makeshift products were difficult to assess and they caused concerns about whether they would meet current regulatory performance standards (Frazer, Shard, and Herdman 2020).

The medical device regulatory authorities across the world responded in different ways to the supply shortages. Nonetheless, the overall effect that they were trying to accomplish was very similar. They all tried to find an effective response to increase the amount of available medical devices during the COVID-19 pandemic. The UK adopted a more flexible approach to regulations during this time. Applications for non-UKCA or non-CE marked medical devices addressing important clinical needs (e.g. ventilators) were processed when no UKCA or CE marked devices were available. To what extend these changes increased the devices available in the market remained unclear. To answer this question, we will focus on two countries (the United States and Australia) for which data is available and explore market registration of PPE devices, as well as devices related to the treatment of COVID-19.

The Food and Drug Administration (FDA) in the United States (US) and the Therapeutic Goods Administration (TGA) in Australia are the governmental departments that are responsible for assuring the safety and efficacy of the medical devices and PPE. We focus on these regulators because there is available data concerning this topic. Accessible and granular data is difficult to acquire in the medical device regulation domain. However, the FDA and TGA have adopted more open standards to data provision, which makes them suitable candidates for this study. Furthermore, both regulatory bodies established pathways so that PPE products could be brought onto the market as fast as possible. Unlike the TGA, the FDA also provided fast-access routes for medical devices (e.g. ventilators), which were used to treat hospitalised COVID-19 patients. The regulatory strategy to provide a faster approval process for ventilators and other medical devices also existed in the UK. These modified regulatory processes were developed to achieve the intended policy goal of increasing the amount of approved devices on the market.

There is an important trade-off between reduction of regulatory obligations and quality control. Medical device regulation standards are set to ensure products meet established safety standards. These criteria are set through consultation with domain experts as well as review of safety data (Chai, 2000). Therefore, reducing the number of obligations has the potential to affect the safety of a device, although this would require specific study on the matter. In the case of the COVID-19 pandemic, there has been concern that the desire to increase quantity has come at the expense of quality (Antonini, 2020).

Currently, there is a lack of data science or regulatory technology applications within the field of medical regulation, despite the potential interesting insights that might be drawn from the available field-specific data (Bergmann, 2022). The fact that we are interested in the number of devices that reached the market indicates that a quantitative approach should be suitable for exploration of this question. Although, it should be considered that a pure quantitative analysis might not be able to provide definite answers without a suitable qualitative assessment. The opposite (qualitative analysis without quantitative evidence) might also be equally true.

This paper evaluates whether COVID-19 related policy changes influenced the number of registered relevant medical devices for a specific country. We will first start with looking at the regulatory response of each country.

The US Response

The FDA wanted to make it easier for medical device manufacturers to make changes to legally-marketed devices and therefore waived the requirement for submitting a 510(k) pre-market notification for some uncleared devices (Food and Drug Administration 2020). A 510(k) is used to demonstrate that a device is equivalent in terms of safety and performance to a device that is already on the market. The waiver included enforcement discretion, for example, for facemasks and protective surgical gowns. The FDA also issued hundreds of Emergency Use Authorizations (EUA) for medical devices, such as in vitro diagnostics, remote patient monitoring devices, ventilators, and PPE (Food and Drug Administration, 2021). It should be noted that the criteria for the issuance of EUAs and their duration does differ from a full FDA clearance or approval (Gerke et al., 2020). In this study will assess the information available in the FDA's Global Unique Device Identification Database (Access GUDID) database (National Library of Medicine, 2021).

The Australian Response

The Australian Government's response to the lack of supplies posed by COVID-19 was to ensure a fast market entry of supplies was possible. Therefore, the medical device regulator in Australia exempted PPE from certain rules, so that these devices could more rapidly obtain approval. (Australian Government 2020, reg. 4). The idea was that this would make essential equipment available earlier and thus enable the country to better manage the pandemic. TGA's Australian Register of Therapeutic Goods (ARTG) will be used for data extraction in this study (Therapeutic Goods Authority, 2021).

Methodology

The proliferation and availability of data in both structured and unstructured heterogeneous forms has spurred the development of analytic methods and techniques, broadly called 'data science'. Data science is extraction of knowledge from data itself, which can be gained via large-scale statistics, machine learning, or other computational analytic methods (Dhar, 2013). The promise of domain specific insights through data science has encouraged adoption of these methods in a wide range of fields, spanning from psychology (Dyer et al., 2018), health care (Fröhlich et al., 2018), and even political science (Wilkerson and Cases, 2018). One area of nascent growth has been the regulatory setting. By 'regulation,' we mean the application of policy directives and rules to a sector or activity. The regulatory setting is understood to contain a mix of policy declarations, legal instruments, as well as data collected about the regulatees which is held by the regulator. Regulatory tasks are therefore ripe for adoption of data science techniques in order to evaluate regulatory efficacy and predict the effects of regulatory actions. However, reliable conclusions from these methods are often challenging because the context of the data (Cai and Zhu, 2015). The data often cannot fully express the context or relationships concerning the underlying data-generation process. This is particularly challenging in areas of implementing data-driven solutions and analyses for government and public services (Janssen et al., 2017). Thus, these methods should not be used uncritically and with full acknowledgement of the limitations.

For this work, we employ a case study of two regulators, using an exploratory data analysis approach. The aims of this case study are to (i) describe any increase in the number of PPE and COVID-19 devices, before and during the pandemic, (ii) to explore if there was a change of WHO-listed devices added to the databases was affected by the regulators' actions and (iii) discuss some preliminary insights with regard to the field of regulatory data science supported by this case study.

Data Description

For this work, publicly available data from the FDA's Access GUDID database and the TGA's ARTG were used.

Access GUDID

Access GUDID is a database of medical devices that have unique device identifiers (UDI). The UDI system allows for identification of devices that are in use in the market. However, not all medical devices approved by the FDA are contained within the Access GUDID database, as the system is currently being phased in. We retrieved information for 2.9 million devices from GUDID

from 30 July 2019 to 24 June 2020. We used the date of publication, the name of the device and the description from the device's Global Medical Device Number (GMDN) to identify the device type and their date of approval. The GMDN provides a broad description of device types and is assigned a unique number, providing harmonisation of descriptions (GMDN Agency 2021). We use the GMDN to identify which listed devices are PPE, COVID-19 devices or other.

ARTG

The ARTG is a publicly accessible database of medical devices approved for use in Australia. An entry in the ARTG contains the device's description, GMDN code, GMDN description, manufacturer, sponsor, classification, and date of registration. The TGA's website states that there are over 90,000 registrations on the register, which includes medicines as well as medical devices. A web-scraper was developed to obtain the ARTG entries, searched for all medical devices registered between 30 July 2019 to 24 June 2020, which resulted in 11,412 devices to be identified. As with the GUDID database, we use the GMDN description and date to identify relevant devices for our analysis.

Pre-processing

Table 1 provides a list of medical devices which are necessary for managing COVID-19 ("COVID-19 devices" for the purposes of this study). It provides an overview of these devices, as well as the context in which devices may be clustered. In addition, PPE was also investigated separate to these other devices. The PPE group includes: (a) masks, (b) goggles, (c) face shields, (d) particulate respirators, (e) gloves, (f) aprons, (g) gowns, and (h) bio-hazard bags.

Table 1: Medical devices for COVID-19 and related context according to the WHO.

Context	Device
Monitoring	Infrared thermometer
	Pulse oximeter
Oxygen therapy	Concentrator
	Mechanical gas cylinder
Airway management	Laryngoscope
	Videolaryngoscope
Mechanical ventilation	Patient ventilator (ICU)
	Patient ventilator (transport)
Non-invasive ventilation	Continuous positive airway pressure
	Bilevel positive airway pressure
	High flow nasal cannula
IV infusion	Electronic drop counter
	Infusion pump
Blood chemistry	Blood gas analyser
Imaging	Ultrasound
Intensive Care Unit	Drill for vascular access

Context	Device
	Electrocardiograph
	Suction pump
Sterilisation	Autoclave

We searched for the GMDN description in the Access GUDID and ARTG data for a match to the devices listed by the WHO. The search resulted in 14 unique GMDN codes for PPE and 21 unique codes for COVID-19 devices within the retrieved ARTG data. The Access GUDID data did not contain the GMDN codes. Instead we relied on the description of terms in order to identify the PPE and COVID-19 devices. Table 2 details the number of identified results in the American and Australian data.

Table 2: Frequency count of the WHO listed devices in the datasets obtained from each database.

	Access GUDID	ARTG
COVID-19 Devices	948	150
PPE	483	1,283

Assessment Methods

We analysed our data using a simple moving average (SMA) tracking the change in device registrations by type over time. SMA is the unweighted mean of a sequence of k data points in a time series (Hansun, 2013). The SMA can be calculated as:

$$SMA_k = \frac{p_{n-k+1} + p_{n-k+2} \ldots + p_n}{k} = \frac{1}{k} \sum_{i=n-k+1}^{n} p_i$$

where p is a data value at i time point, with n representing the total number of data values available. In our study, we investigate the period between July 2019 to July 2020, selecting a 10-day and 20-day window size for k.

Results

Figure 1 and 2 show the monthly registrations in the data from July 2019 to July 2020. There is a clear difference in the ARTG data as seen in Figure 2. It shows an increase in all device types after the WHO declaration of the COVID-19 pandemic. Figure 1, which shows the FDA data, remains more consistent and neither increases nor decreases much due to the pandemic.

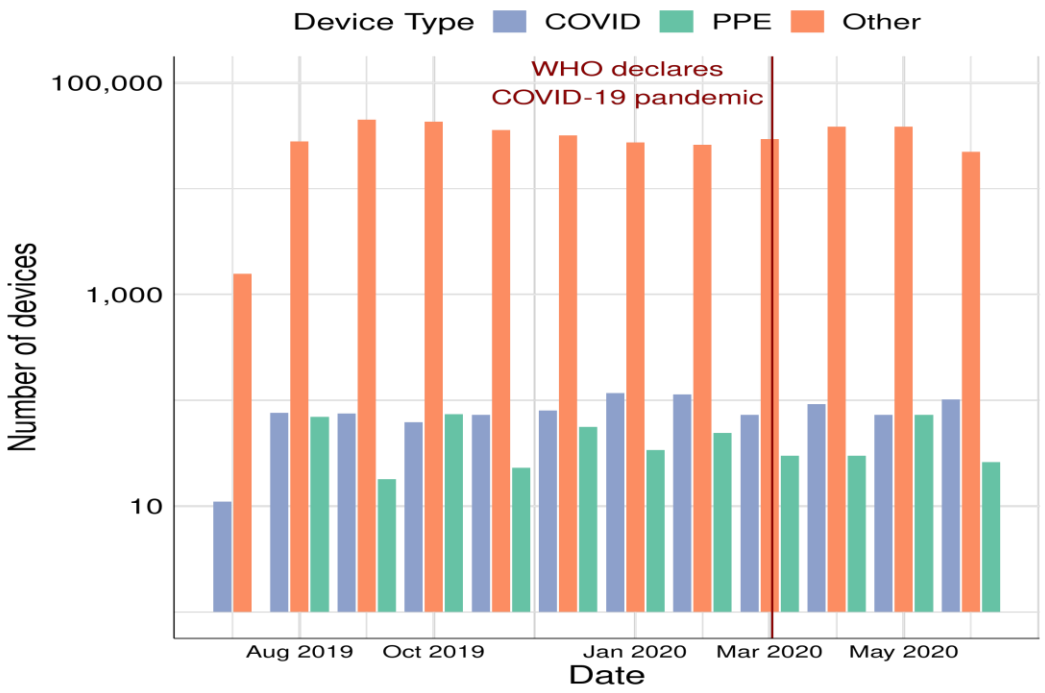

Figure 1: The monthly registrations of devices in FDA's Access GUDID. Three devices types are shown.

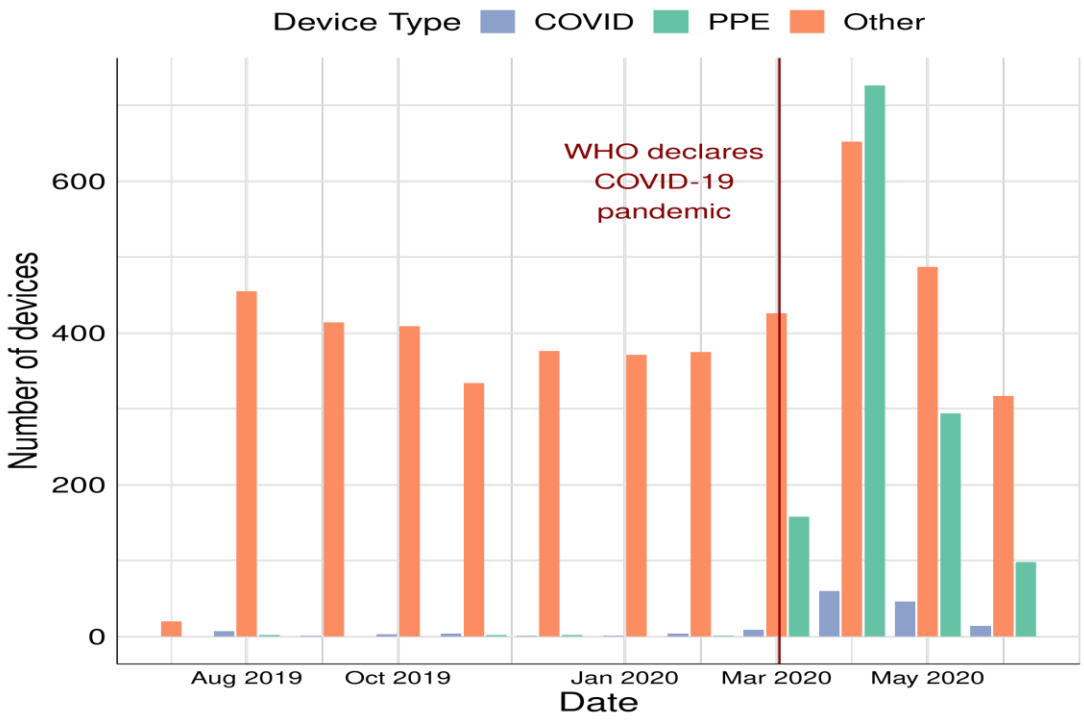

Figure 2: The monthly registrations of devices in ARTG. Three devices types are shown.

To visualise the changes in registrations in a more granular detail (January to mid-June 2020), the moving averages of the COVID-19 and PPE device types are shown in Figure 3 and 4. In Figure 4, the PPE devices registrations experience a sharp increase, but then decreases rapidly. The COVID-19 devices registrations increases (albeit modestly) and then remains higher than prior to the pandemic.

The Access GUDID data from the FDA shows some subtle changes during the time period for both the 10- and 20- days moving averages in both COVID-19 and PPE device types (see Figure 3). For COVID devices, the GUDID data has a marginal increase at the start of the pandemic, but then drops around April 2020. These devices begin to increase again in June 2020. The PPE devices in the GUDID data do not meaningfully increase or decrease until the end of May 2020, where there is a small uptick, which then falls by the subsequent month.

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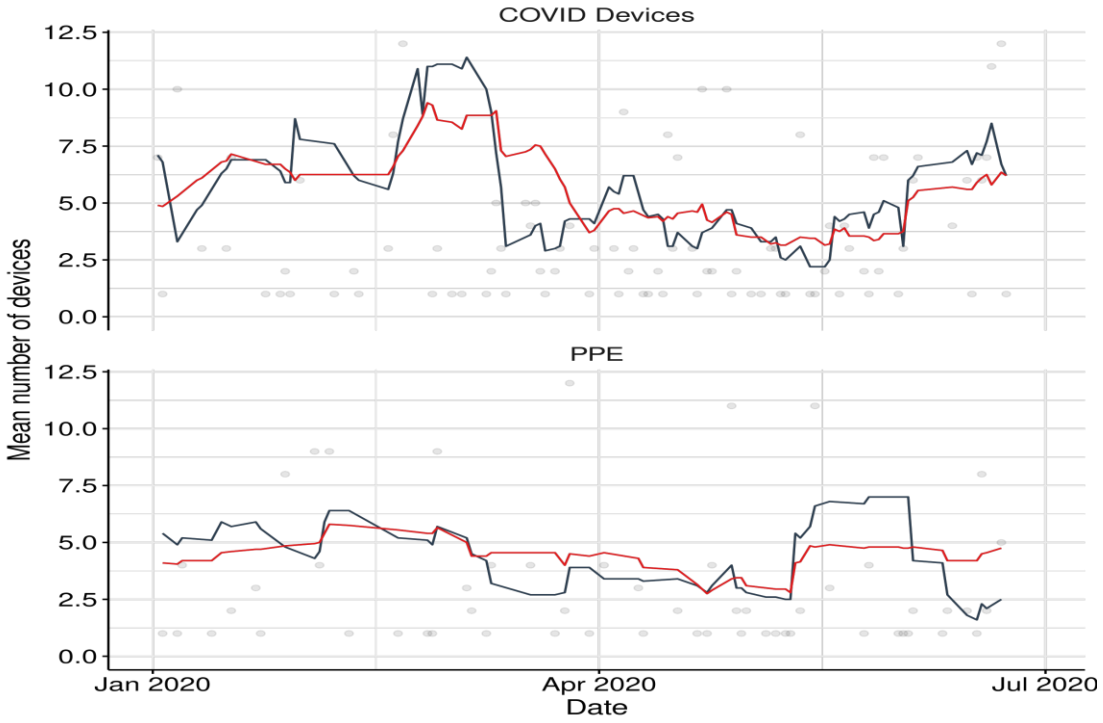

Figure 3: Registration of all relevant medical devices in the FDA's Access GUDID data. The blue (10-days) and red (20-days) lines show the corresponding simple moving average (SMA).

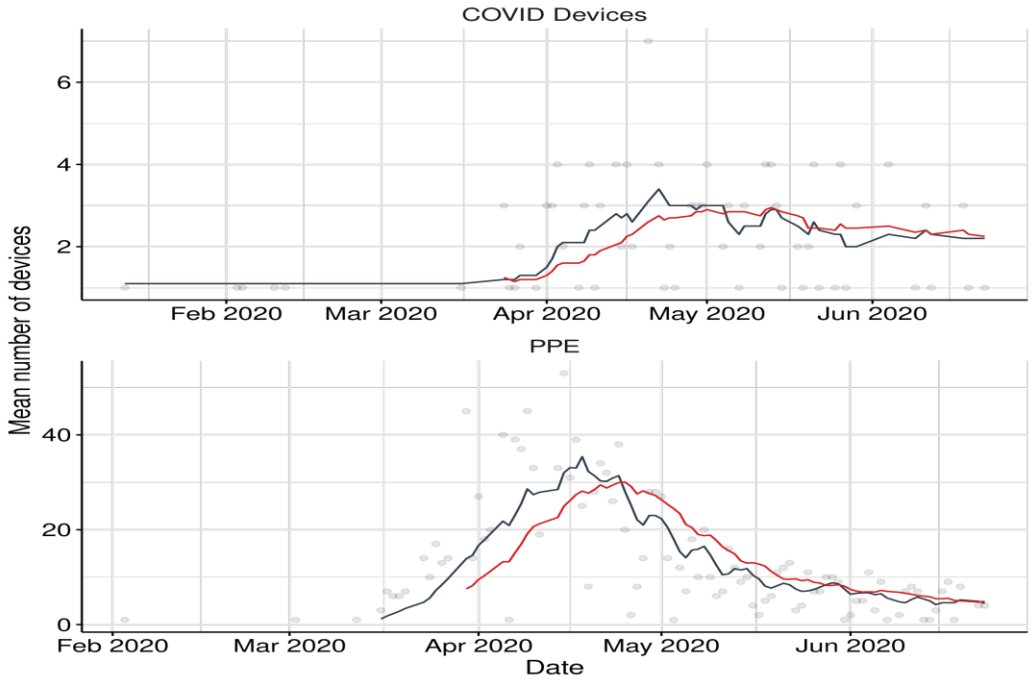

Figure 4: Registrations of all relevant medical devices in the ARTG data. The blue (10-days) and red (20-days) lines show the corresponding simple moving average (SMA).

Discussion

This study found differences in registered devices between the two databases explored. However, a number of considerations need to be taken into account when applying data science techniques in regulatory environments. In the discussion below, we will first briefly discuss the outcome of the analysis and then turn attention to potential pitfalls and caveats.

The ARTG results indicate a notable increase in registrations in both PPE and COVID-19 devices in Australia during the August 2019 – August 2020 period. However, it is recognised that COVID-19 devices and PPE are fundamentally different. In general, PPE has a lower risk class, making it difficult to group PPEs together with more complex, higher risk items, such as ventilators. This qualitative difference in the device types may also influence the rate of inclusion of new COVID-19 devices and PPE. Furthermore, we emphasise that increasing the supply of legally marketed devices is not the same as bringing newly-cleared or approved devices to the market. In the Australian context, the legislation allowed for PPE to be fast-tracked for approval and inclusion in the ARTG. As such, the outcome of the Australian policy is striking, as there is a sharp rise of the types of PPE products that were made available. This kind of data analysis can thus be used to help determine if policy changes yield the desired effect. It also allows stakeholders to discuss beforehand what the preferred outcomes should be and determine if or how these are measured throughout a certain period. Determining what a measurable/desirable outcome might be is not always easy to agree upon, but if all stakeholders do have a clear outcome in mind then the data can help in assessing if the final result is obtained in the end.

The Access GUDID data, by contrast, does not show particularly dramatic changes in the overall registration of devices. We propose two possible explanations for this. First, the Access GUDID data is limited, as it contains only approved items, which limits the possible data analysis that can be performed. Many devices which are legally marketed are not included in the data set that was explored. If a high number of PPE and COVID-19 devices are 510(k) exempt then this will have an effect on the conclusions that can be drawn from this data. This is exacerbated by the fact that EUA devices are also not included in this data set. Taken together, this could mean that the overall effects of the policy are not fully represented within a single database. This indicates the importance of creating regulatory databases that are all encompassing.

Medical device regulations exist to ensure that devices reach appropriate standards of safety (Bartoo, 2003). This is necessary and vital to the provision of quality healthcare and achieving positive clinical outcomes. Thus, expediting approval for devices may impact the safety of the devices. In this study, we are unable to assess whether the expedition of the PPE or COVID-19 devices reached the same standards as similar devices which were not subject to the expedition policy. The COVID-19 pandemic highlighted the pitfalls of the ‘just-in-time’ model preferred by the industry. Not only were the availability of the supplies limited, but there may be potential degradation of safety standards in order to make up the short-fall. There is a need for preparation strategies in order to avoid not only having healthcare providers lacking fundamental equipment but also reducing the necessity of considering expedition of devices which can affect safety standards.

The application of mixed methodologies have rapidly evolved in other fields (Kelle, 2006). The data-driven analysis of regulatory policy can help inform both policy actions and procedures. The value of applying data analysis is further strengthened by the increase demand for governmental bodies to do more with their data. This is also true for the medical domain, which is grappling with questions regarding how data science may be incorporated given the legal and ethical issues inherent within the health care space (Gerke, Minssen, and Cohen, 2020). Access to large, heterogeneous sources of data maintained by regulatory bodies may spur further medical device innovation (Erdman, Keefe, and Schiestl, 2013). While there have been initial applications of data-driven approaches to analysis of medical device regulation (Bergmann, Hendricusdottir, and Lee, 2019; Ceross and Bergmann 2021; Arnould, Hendricusdottir, and Bergmann, 2021), these have not yet reached a substantial presence within either the regulatory or data science literature. This research adds new findings to this emerging new field, but further investigations are still needed to obtain a well-rounded understanding of the impact that policy changes can have within the healthcare domain. The Medicines and Healthcare Products Regulatory Agency (MHRA) in the UK has the intention to introduce new medical device regulations by July 2024. The ability to review historic data provides an opportunity to assess the effect of previous regulations and can help inform future UK regulations.

Challenges for a regulatory data science

This work raises important points concerning the data provided by medical device regulators and the potential use of this data by researchers. The context of the data is not always readily clear from a provided regulatory data set. For example, it is not necessarily obvious from the description of the current American data that many legally-marketed devices were not included in the FDA's Access GUDID database. The aim was that all devices would have been included, yet at present this is not the case. Therefore, the data can only present part of a wider story. Not being aware of these nuances would lead to an incorrect interpretation of the data.

The field would greatly benefit from more data specifically structured for research use. This will require academics to work together with governments and other stakeholders. It will also mean that researchers need to start to convey the need and possible impact of such endeavours in order to gain traction. The ability to make regulatory policy decisions more quantitative could save time and money when implemented correctly. This is a strong incentive for all stakeholders to start working together to create more open access databases.

Conclusions

In this study, we have visualised data from medical device regulators to explore the effects of policy changes on relevant medical devices registrations during the COVID-19 pandemic. In the case of Australia, the results suggest that the policy had the desired effect of increasing PPE manifold over its previous rate. In addition, even though there were no special permissions needed for COVID-19 devices, the Australian data showed an increase in the inclusions of such medical devices, even though it was more modest compared to PPE. This simple result can have wide utility, as it provides an insight that is not identifiable purely from policy documents or qualitative assessment.

The effect of policy changes was not directly evident in the American data. As the data set available from the FDA did not capture relevant information from all legally marketed devices. This might not be readily apparent, as the data is comprised of millions of records spanning many years. The data even captures incredibly granular information about the medical devices. However, the size of a data set is no guarantee of its utility. Without knowledge about the regulatory space in the US, an erroneous conclusion might be drawn from sole reliance on this data. In the American case, there are other factors at play which are not represented in medical device regulatory data. This highlights the need for multi-disciplinary approaches within regulatory data science. Better management of access to appropriate medical technology can be informed by such a multi-disciplinary effort.

Furthermore, these results show how interesting new questions can be posed when data science is applied in fields such as regulations. There is a need for an effort across stakeholders to provide better data, more training and too also broaden their perspectives as to how insights can be generated. However, it is encouraging to see a growing interests of regulators themselves in how best to manage their data for maximum effect. There is little doubt that data science will play an ever-increasing role in the regulations of the future making it an interesting field for scientists to engage in. We also note, however, that these methods are not a panacea nor to be uncritically adopted. Data science is limited by the data that is collected. The design choices in the data schema may limit the conclusions that can be derived from its analysis. Furthermore, mixed methodologies (e.g., using qualitative assessments and computational methods together) are able to provide more comprehensive perspectives but requires acknowledgements of the limitations of each. Additionally, there are challenges in acquiring sufficient expertise in each discipline and costs of time. Despite this, we remain encouraged by the continued provision of data by regulatory authorities, which allows for the development of new approaches.

Supplementary Material

The analysis script and data may be found at https://github.com/Oxford-NIL/covid-policy-impact.

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