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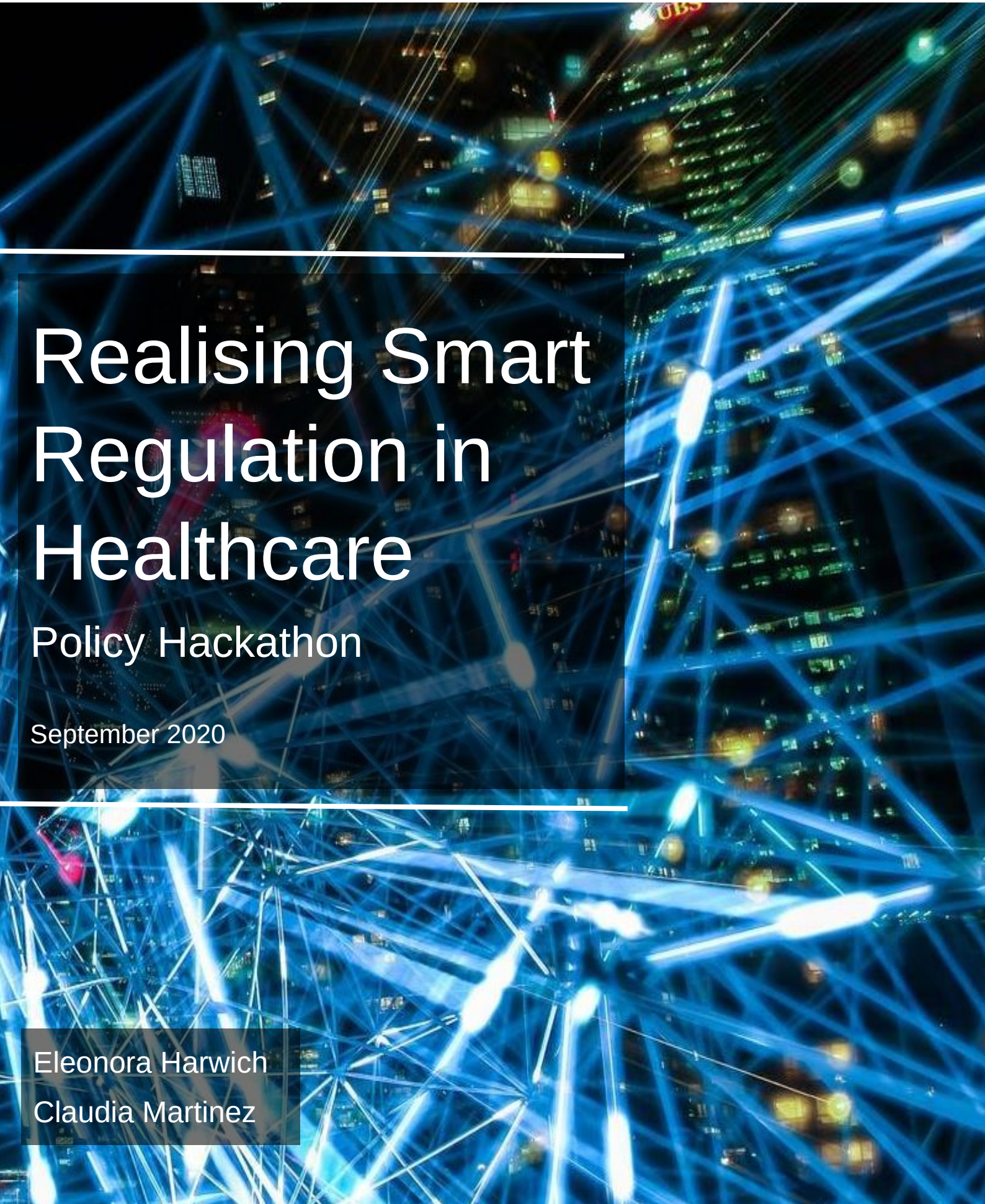

Realising Smart Regulation in Healthcare

Policy Hackathon

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Realising Smart Regulation in Healthcare

In late 2018, Matt Hancock, Secretary of State for Health and Social Care, set out his vision for the creation of a tech-driven NHS and for the UK to become a world leader in healthcare technologies.[1] Central to making this vision a reality is smart regulation. As highlighted by Matthew Gould, CEO of NHSX, in February 2020, “doing AI right means putting a set of rules around it that will make sure it is done safely”.[2] Unfortunately, regulation is often viewed as a burden or barrier to innovation. This is particularly true in an area like data-driven innovation in healthcare as the regulatory process can be confusing due to the number of rules and bodies involved in the process.

To remedy this, *Reform* worked in collaboration with NHSX to produce a map – amongst other resources – highlighting the regulatory requirements at each stage of the innovation process and the role of each regulator and statutory body given that regulatory requirement. This enabled us to identify certain issues and bottle necks with the innovation and regulatory process.

On July 22nd 2020, *Reform*, in partnership with Imperial College London’s The Forum, held a virtual Policy Hackathon on the topic of "Realising Smart Regulation in Healthcare". Building on the award-winning research *Reform* produced in collaboration with NHSX, the event convened a leading group of experts including healthcare regulators, statutory bodies, NHS leaders, academics and innovators, to propose solutions to specific challenges identified in the regulatory pathway for data-driven healthcare innovations. This report presents a summary of the main solutions discussed by attendees. Hackathon participants were asked to work through specific policy challenges organised across four domains:

01 | Data access

02 | Proof of concept & evidence building

03 | CE marking & post-market surveillance

04 | The overall regulatory process

Reform and The Forum would like to extend its thanks to participants of the Policy Hackathon for their work and ideas to make this document possible.

[1] https://www.gov.uk/government/speeches/my-vision-for-a-more-tech-driven-nhs

[2] https://healthtech.blog.gov.uk/2020/02/12/regulating-ai-in-health-and-care/

Contents

01 | Data access

POLICY CHALLENGE I – who holds what data?

Innovators can find it challenging to know what type of data is held by which health and care organisations (e.g. NHS Trusts, Commissioning support units, etc.) and which data is accessible to them. This can have an impact on the success of a data access request as innovators might be asking for more data than what is needed or might request data that does not exist.

SOLUTIONS

- Data controllers should publish metadata about datasets they hold and explore the possibility of releasing dummy or synthetic versions of datasets to innovators and researchers prior to formal data access request. This would help individuals and organisations to have greater visibility over the types of data held by health and care organisations. It could also potentially improve the success rate of data access requests as it would be easier for individuals to abide by the data minimisation principle in data protection regulation as their data access requests could be made more specific.
- Attendees suggested that an existing trusted third-party broker (e.g. Health Data Research UK's Digital Innovation Hubs, Local Health and Care Record Exemplars, NHS Digital) who has coverage across a wide range of data sources could act as the 'single front door' for accessing it. The role of the broker would be to direct innovators and researchers to the most appropriate data source for a given project.

SUCCESS FACTORS FOR IMPLEMENTATION

Robust information governance (IG) frameworks are required to successfully implement any model seeking to provide a single 'front door' for data. Whether led by the Digital Innovation Hubs or other localised body, effective IG is critical to build and preserve trust between the data broker, innovators, the public and the health and care organisations holding the data, as well as to avoid conflicts of interest.

Implementation of such models will also require close consideration of commercial models and any intellectual property (IP). It is paramount to ensure that public trust is retained. Communication must be honest about the benefits and risks of accessing data for research and/or product or service development purposes.

Establishing these trusted third parties who would direct innovators and researchers towards the most appropriate source of data for a given project would need to perform some groundwork to establish a view of the health and care data landscape.

POLICY CHALLENGE II – data quality

Prior to accessing data, innovators do not have information about data quality (i.e. coverage, integrity, timeliness, completeness, validity, how the data has been codified – using SNOMED CT or other type of clinical coding standard.) This information asymmetry can cause delays in projects as more time might be needed to appropriately clean the data than initially planned. In addition, it prevents from having an early understanding of the limitations/biases the data might have.

SOLUTIONS

- To improve accuracy and reduce bias in data-driven technologies, data controllers should provide contextual information about how data is collected and what the quality of that data is. Information about data quality could follow NHS Digital's framework for the Data Quality Maturity Index. Depending on how cumbersome this would be, health and care organisations could implement this as a fee-paying service.
- Data controllers should publish schemas (the structure for organising and classifying data in a database), metadata and restrictions on data use. This would help build a better understanding of the quality of the data and mitigate against issues with data linkage due to different coding structures. Guidelines about these schemas and metadata frameworks could be published central body like NHS Digital or NHSX in the interest of standardisation.

SUCCESS FACTORS FOR IMPLEMENTATION

Improving data quality in the health and care system will require building capability for local organisations to minimise errors at the point of collection. This might take the form of staff training or finding ways to reduce the burden of data collection on frontline practitioners through automation or well designed and intuitive data collection platforms.

POLICY CHALLENGE III – GDPR and Common Law

The General Data Protection Regulation (GDPR) and the Common Law Duty of Confidentiality can sometimes appear to be conflict with each other. This can create difficulties in understanding how to uphold confidentiality and knowing when data can be shared lawfully. Although there is guidance from the Information Commissioner's Office (ICO) and the Health Research Authority (HRA) on GDPR and the duty of confidentiality – to help people interpret "public interest" as a lawful basis for processing confidential patient information – issues still exist. There is a lack of clarity regarding the legal basis which can be relied on to use the Article 9 exemptions under GDPR for the processing of special category data (these exemptions refer to scientific research "based on Union or Member State law"). In addition, current guidance focuses on the scientific research exemption, rather than considering when the "public interest in public health" exemption might be relied on to process special category data (e.g. ethnicity, genetic data, etc.).

SOLUTIONS

- A dialogue must be established at a local level to assess the public's "reasonable expectations" concerning how data about them is shared and used, and for which purposes, when obtaining consent from them is not a practical route. Patient groups should be consulted as they can offer in-depth insight into the practical implications in the context of a specific illness and attitudes to data use.
- The ICO and HRA should publish guidance clarifying the tension between the Common Duty of Confidentiality and the GDPR. The local public dialogues about could be used as a basis to clarify this tension. It would give a greater 'social licence' to the various legal bases that can be used to share and process data when consent is not a practical route.

POLICY CHALLENGE IV – Secure access to data

Privacy Enhancing Technologies (PETs) and encryption techniques could enable the sharing and use of data in a privacy-preserving and trustworthy manner. These are nascent technologies, and therefore in the early stages of maturity. Currently, there are no regulatory guidelines on how the use of 'mature' PETs can help mitigate privacy risks, risks of data protection, etc.

SOLUTION

- PETs must be implemented as part of the wider governance framework for data-driven healthcare. To ensure that PETs are used appropriately, the limitations of these technologies must be made explicit. This could be best achieved by recommending or mandating the use of international standards (e.g. ISO 25237:2017), publishing and disseminating guidance and case studies on the use of PETs.

SUCCESS FACTORS FOR IMPLEMENTATION

PETs can potentially help in overcoming important security challenges in the sharing and use of data in the context of data-driven healthcare innovations, but it should not be seen as a panacea. Improved awareness of what these technologies can and cannot do, and for which purposes, is needed to ensure that they are employed appropriately and that users understand the impact PETs can have on data 'utility'. Expanded professional training and awareness of what constitutes responsible data use is needed.

02 | Proof of concept & evidence building

POLICY CHALLENGE I – Evidence standards for CE-marked devices

There is a lack of clarity as to what constitutes sufficient 'clinical evidence' to demonstrate compliance with CE marking under current regulation. The New Medical Device Regulation (MDR) 2021 (operational date) and In-Vitro Diagnostic Medical Devices Regulation (IVDR) 2022 (operational date) is going to introduce expert panels to help assess high-risk devices and stipulate the evidence needed before their CE marking. However, there is some uncertainty as to what will happen post-Brexit, as expert panels are appointed at EU Commission-level.

SOLUTIONS

- The UK is negotiating several new trade deals which will determine how products and services are traded between the UK and other countries. The process should preserve the ability for these trade deals to determine that devices certified in non-UK markets can be allowed to enter the UK market, or that the UK's process allows devices to enter non-UK markets, whilst ensuring the high-quality standards.
- The UK should maintain a collaborative relationship with regional regulators across the EU and worldwide (e.g. the Food and Drugs Administration in the US and International Medical Device Regulators Forum) to share learnings. This joint working and collaborative approach should be maintained post-Brexit.
- Participants suggested that expert panels should reflect a diversity of skills and experience from clinical, public health, engineering, industry, IT to security in order to judge potential impacts of new technologies. They also recommended that bodies like the Medical Royal Colleges, the Faculty of Clinical Informatics and the ICO should be involved. In addition, regulators should establish a dialogue with the public about how their data may be used when monitoring device safety.

SUCCESS FACTORS FOR IMPLEMENTATION

Setting up and implementing the expert panels will require new skills and expertise both within the Medicines and Healthcare products Regulatory Agency (MHRA) and the other academic, statutory, regulatory and professional membership bodies participating in the process. Suitable expertise might need to be sought out internationally if unavailable within the UK. Further, appropriate resource and investment must be made available for the MHRA to set up and run the expert panels.

POLICY CHALLENGE II – Routes to clinical evidence

There is a lack of clarity regarding the different routes for manufacturers to collect clinical evidence to prove the safety and performance of their product. Manufacturers can often find themselves unable to discern between which evidence collection methods are most robust or effective. For instance, a manufacturer might have to run a controlled trial as part of the performance evaluation for a data-driven technology, unless an equivalence can be shown to devices already on the market. This is unlikely unless manufacturers have access to the source code of the "equivalent" device.

SOLUTIONS

- The MHRA and the National Institute for Care Excellence (NICE) should establish best practice for clinical evidence gathering standard and produce a decision tree to direct start-ups and healthcare innovators to the types and level of evidence required to prove the safety and efficacy of their data-driven product(s). These evidence standards should also be coupled with a robust risk management process to assess the risk profile of a product. Guidelines from the International Medical Device Regulators Forum for risk management and classification of software products could be used as a basis for national evidence standards. The latter should be produced in collaboration with academia, statutory bodies and industry, and must consider the appropriateness of a variety of evidence-collection methods and how they should be operationalised in different contexts. For instance, the use of randomised control trials for gathering clinical evidence and/or operational data for validating algorithms.

- NHSX should support the creation of an open learning programme to help innovators understand the most appropriate evidence required from an industry perspective to support possible future collaborations and streamline clinical evidence pathways.

- Testbeds and expert evaluation testing centres should be set up to enable innovators to access data for testing and validation. These centres could be modelled on the National Institute for Healthcare Research's (NIHR) Medtech and In vitro diagnostics Co-operatives (MICs) and run under the supervision of NHSX. Organisations like the NIHR or Health Data Research UK focus on the delivery of these testbeds.

SUCCESS FACTORS FOR IMPLEMENTATION

Well-established PETs, such as distributed machine learning, must be harnessed to enable the secure sharing of data for testing and validation of algorithmic models. Use of techniques like 'procedural encryption' would allow sharing code with third parties in a controlled and safe manner. Similarly, the use of distributed privacy technologies could help share code to secure data repositories.

POLICY CHALLENGE III – Evidence for CE-marking and evidence for commissioning

While the decision to award a conformity mark and the decision to commission a product or service should remain distinct there is an opportunity to align the evidence that is required for the CE marking process and the evidence that is then required for commissioning purposes or development of NICE guidance.

SOLUTIONS

- NICE and the MHRA should undertake a joint project aimed at identifying opportunities to harmonise existing standards. This would help deliver a more cohesive landscape for innovators seeking to evidence the safety and performance of their data-driven device(s) and get it commissioned by the NHS. New approaches to partnership working between the MHRA and NICE are expected to become more embedded as the UK leaves the EU.

- The use of tools like NICE's PICO (population, intervention, comparator and outcome) framework should be further promoted to help innovators develop well-formulated review questions and evidence regarding the effectiveness of an intervention or technology.

- Consideration of endpoint security technologies should be introduced early on as part of the innovator's evidence building pathway for NHS commissioning and reimbursement.

SUCCESS FACTORS FOR IMPLEMENTATION

Good collaboration between the MHRA and NICE will help to establish where evidence standards for safety and cost effectiveness can be harmonised. A clear dissemination strategy of these results through the development of accessible resources for innovators will be key.

03 | CE marking & post-market surveillance

POLICY CHALLENGE I – Lack of standardised framework for AI algorithms

There is no harmonised standard for validating AI algorithms under current directives (IEC 82304-1:2016 includes validation for health software & forthcoming edition of IEC 62304 will include a requirement for algorithm change protocol). Regulators have not yet found a way to assess the regulatory compliance of certain types of algorithms, particularly those using machine learning.

SOLUTIONS

- Standards for validating algorithms must consider (a) whether the model is 'static' (i.e. once it has been trained the algorithm is 'fixed' and does not learn or change with new data inputs) or 'live' (i.e. algorithm continuously learns and evolves given new data inputs in a real healthcare setting); and (b) whether the algorithm is a clinical decision support tool (i.e. decision about course of action to follow lies with a healthcare practitioner) or automated diagnostic tool (i.e. no human in the loop). Regulators should look at both the intended use and methods for assessing safety performance of current CE marked 'static' algorithms and seek to harmonise standards accordingly with a robust risk assessment process.
- Despite it not always aligning with current CE-marking regulation, the MHRA could explore the work that the US Food and Drugs Administration (FDA) has done concerning the regulation of 'live' algorithms in healthcare. The MHRA could consider the FDA's work in the light of post-transition guidance.
- Synthetic data can be produced in order to validate algorithms and its use should be considered when harmonising standards for 'fixed' algorithms. NHS Digital and the MHRA's joint project on synthetic datasets will build increased capability for measuring the effectiveness of algorithms and machine learning innovations and could be used to inform the regulatory framework.
- Adoption of the 'Shared Tasks'[3] commonly used in AI research by companies and academics could enable faster evaluation of algorithms. This model allows for a problem to be shared online and the research community can respond by finding solutions to that problem. Evaluation protocols for algorithmic performance could be derived from such an approach.

[3] https://www.mitpressjournals.org/doi/pdf/10.1162/COLI_a_00304

SUCCESS FACTORS FOR IMPLEMENTATION

Frameworks to evaluate algorithmic performance should not follow a one-size-fits-all model, but rather should vary depending on the intended use of the device. The evidence needed for assessing compliance with the regulation must not only be proportionate to risk but also needs to take account of other characteristics of the algorithm, including transparency and explainability, adaptivity and expertise of the user.

POLICY CHALLENGE II – Definition of a system

The MDR's current definition of a system is "a combination of products, either packaged together or not, which are intended to be interconnected or combined to achieve a specific medical purpose". This means that when bolting devices or accessories into an existing system, the regulation does not cover the system as a whole unless the medical devices and accessories are placed on the market together. How should whole systems be regulated? What should be regulated? What evidence is required to establish the safety and effectiveness of each element and in combination?

SOLUTION

- Participants highlighted the importance of the manufacturers' responsibility in understanding how their device might be used in a real clinical setting and reflecting that back in the intended use of the device (see IEC 62366). Manufacturers should have reasonable understanding of how their device might be used in combination with other devices in the clinical setting and assess which combinations are safe. Current regulations allow for a defining system by using a product's claims and instructions for use.

SUCCESS FACTORS FOR IMPLEMENTATION

Participants highlighted that algorithms are part of larger socio-technical systems and their impact can go beyond their accuracy levels. A better evaluation needs to take into account the context in which they are used and showcase a deep understanding of the clinical setting. Intended uses written by manufacturers might not be practical in the clinical setting leading users to deviate from intended uses, these behavioural impacts need to be taken into account by manufacturers.

POLICY CHALLENGE III – Operationalising explainability

Recital 71 of GDPR includes a 'right to explanation' of decisions made by automated or artificially intelligent (AI) systems. The Information Commissioner's Office (ICO) and The Alan Turing Institute are collaborating to create practical guidance to assist organisations with explaining AI decisions to the individuals affected. However, there are explainability requirements in the regulation of devices. The manufacturer needs to be able to explain the algorithm to show that they follow regulations.

SOLUTION

- Participants highlighted that explanability in healthcare needs to take into account four main factors:
    - The level of autonomy of the algorithms is it a decision support tool or is it a decision-making tool? This will carry hugely varying explainability requirements
    - The level risk and harm the algorithm could inflict.
    - The breadth and complexity of the clinical problem it is trying to solve.
    - The skills and experience of the intended end user

  Taken together these factors can help inform decision about what might need explaining, how much needs to be explaining and how it might to be explained.

SUCCESS FACTORS FOR IMPLEMENTATION

Frameworks for explainability of algorithms in healthcare have to be designed in a flexible way so that they can be adapted to specific use cases.

POLICY CHALLENGE IV – Changes in risk classification of devices

The New Medical Device Regulation (MDR) 2021 (operational date) and In-Vitro Diagnostic Medical Devices Regulation (IVDR) 2022 (operational date) will have an impact on the risk classification of devices. Many devices & software will be upclassified based on a reassessment of risk (i.e. a vast number of these devices will now require a Notified Body as their classification increases). The IVDR 2022 will introduce a whole new risk classification system. This is likely to have an impact on the Notified Bodies' capacity to carry out conformity assessments due to increased demand & to the fact that there are only a few Notified Bodies in the whole of Europe who can provide accreditations under MDR & IVDR. Current providers with CE marking that need to be upclassified are struggling to obtain a Notified Body due to capacity constraints.

No clear solutions were reached by attendees during the Hackathon due to uncertainties around Brexit negotiations. On 1st September 2020, the MHRA published some updated guidance,[4] which clarifies this tension point.

[4] https://www.gov.uk/guidance/regulating-medical-devices-from-1-january-2021#UKCA

04 | The overall regulatory process

POLICY CHALLENGE I – Lack of coordination & oversight

Currently, there is no system in place to help regulators coordinate and make the regulatory pipeline for data-driven technologies into a seamless one. There are many regulators and statutory bodies that play a different role at various stages, but there is no mechanism that allows regulators, statutory bodies or entrepreneurs to track the progression of the whole process or even know what the whole process is.

SOLUTIONS

- Regulators should draw lessons from existing attempts to enable regulatory coordination, including the UK Government's Regulatory Horizons Council and the Digital Markets Taskforce led by the Competition and Markets Authority. Assessment of the challenges faced by other sectors/industries that have implemented AI and the solutions they have adopted to enable better regulatory coordination could help inform this work.
- Healthcare regulators could work together to produce a single set of guidance or map that sets out what the regulatory pathway for data-driven technology is and all the relevant regulations that innovators need to follow. This would be an inexpensive solution, which would also help optimise coordination and communication between regulators. Tools like the 'UK data governance landscape explainer' produced by the Royal Society or the work that *Reform* has done in collaboration with NHSX could serve as a template for this.
- In the long term, participants discussed the possibility of extending the use of the Integrated Research Application System (IRAS) number for research, which currently exists between the HRA and MHRA, to other regulators. A platform could be designed so that innovators have a single portal through which they can track their progress on their regulatory journey. Participants also mentioned that the Global Medical Device Nomenclature could be drawn on as an example to develop this platform.

SUCCESS FACTORS FOR IMPLEMENTATION

Promoting better coordination and communication between healthcare regulators is essential for making the regulatory pathway clearer and more streamlined for innovators. To make this happen, responsibility for coordination activities must be allocated either to an existing regulator or expert steering group. This body would also ensure that dialogue is maintained with industry about the specific regulatory issues they might be facing and the innovations coming through the regulatory pipeline. Better coordination also requires developing shared knowledge and language amongst regulators, for instance, on areas such as quality. The work that the Care Quality Commission has done as part of the Quality Matters initiative, as well as the 'Shared commitment to quality' from the National Quality Board, are good examples of this.

POLICY CHALLENGE II – No registry of CE-marked devices

There is currently no consolidated registry of CE marked devices and in vitro diagnostic medical devices held by regulators (e.g. MHRA & Notified Bodies) which means they cannot keep track of products or do proactive random inspections of devices. Information about CE marked devices is kept confidentially by notified bodies. With the New Medical Device Regulation (MDR) 2021(operational date) and In-Vitro Diagnostic Medical Devices Regulation (IVDR) 2022 (operational date) there will be an EU-level registry of medical devices and in vitro diagnostic medical devices, there should also be a UK register of new devices post-Brexit, but not on the same scale as EUDAMED.

SOLUTIONS

- On 1st September 2020, the MHRA published updated guidance,[5] which provides a solution to this tension point. However, here are the solutions attendees had come up with:
    - Post-Brexit, and in a deal scenario, the UK should be granted access to the EUDAMED database for post-market surveillance activities.
    - Post-Brexit, and in the case of a no-deal outcome, the UK could create a national version of EUDAMED which could include information about approvals by other regulators. This could become a unique UK asset.
    - Develop a mixed system comprising EUDAMED alongside a UK specific registry for post-market surveillance. This, however, might result in higher costs for companies who will need to keep separate registries. Issues could also arise concerning the validation/accuracy of the information inputted into these systems and the ability to update the databases with additional information.

SUCCESS FACTORS FOR IMPLEMENTATION

There is a high degree of uncertainty as to what solution should be implemented due to Brexit negotiations. It is however crucial that the UK retains a pragmatic and holistic approach to regulation by having a clear understanding of what procedures can optimise both patient safety and reduce cross country regulatory variation and burden.

[5] https://www.gov.uk/guidance/regulating-medical-devices-from-1-january-2021#UKCA

POLICY CHALLENGE III – Contract variation

There are differences in how people interpret information governance, data protection and there is a lack of standardisation of data sharing agreements between health and care organisations and the private sector. This leads to unnecessary variation in data sharing practices with some health and care organisations being more willing to share information than others.

SOLUTIONS

- Regulators like the HRA and ICO and executive agencies like NHS Digital should ensure greater clarity regarding the different roles in a data sharing agreement when applied to the healthcare context by providing clear case study examples of the different rights and responsibilities as data controller, joint-controller and processor.
- The Department of Health and Social Care, the ICO and NHSX should provide greater clarity around the definition of different types of data in the healthcare context. This would mean clearly defining what is personal identifiable data, what is de-identified data, what is pseudonymised data and what is anonymous data.
- The DHSC, in conjunction with NHSX & NHSE/I, could create a menu of options of what should be in a standard data sharing agreement with clear guidance on the questions that need to be thought through when setting up a data sharing agreement.
- Publish case studies and examples of best practice but also ‘common mistakes’ and failures in the development of contracts and data sharing agreements for data driven technologies in healthcare. Responsibility should be shared between healthcare regulators, with the support of the ICO. Existing structures and programmes, such as the Digital Innovation Hubs and the ICO’s regulatory sandboxes will be instrumental in informing and implementing new guidance.

SUCCESS FACTORS FOR IMPLEMENTATION

To ensure that guidelines are fit for purpose and kept updated, a review schedule should be established and implemented with the input of the relevant healthcare regulators. This work must be supported by appropriate investment as well as specific resource to ensure that guidelines are disseminated and shared to innovators and health and care organisations.