Rigid Power Structures: Barriers Undermining the Impact of Machine Learning in Nursing

Will the use of Machine Learning be an opportunity for the diversification of Diagnosing and Decision Making Roles in Japan?

「硬直化したパワーバランス：看護における機械学習の活用の障壁」

ー機械学習の活用は診断・意思決定者の多様化へのきっかけとなるか?ー

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Abstract

Background: Many consider Artificial Intelligence (AI) to be the next big revolution in healthcare. Consequently, there are numerous examples of AI research pertaining to its application to medicine. However, there exists a gap in research pertaining to the application of AI to nursing, especially in the field of nursing policy in Japan.

Purpose: The central purpose of this study was to investigate AI's potential impact on the role of nurses and its related policies in Japan and identify structural impediments in Japanese healthcare that could hinder the realisation of such potential benefits. Following the multiple sampling processes that reflect the grounded theory approach, this purpose was progressively reassembled into three main objectives, namely: i) the exploration of AI (particularly Machine Learning: ML) functions in healthcare, ii) investigation of policies and legal structures that define the role of nurses in Japan, and finally iii) the identification of policy choke points that could be cleared through the application of AI in nursing, and the presentation of policy proposals that could expedite its implementation.

Research Method: The research utilised a grounded theory approach, which consisted of an initial purposive sampling process, and two rounds of theoretical sampling processes. New themes extracted during each sampling process were utilised to formulate hypotheses and research questions for the following round. In total, the study employed a literature review of 210 documents, 7 individual interviews, and 1 group interview.

Extracted Themes: Five major themes were extracted from the three sampling processes. 1) The existence of a power gradient between different healthcare professions, fixed in healthcare policy. Moreover, these policies and legal structures do not necessarily delineate tasks between professions, but rather serve to consolidate decision making authority onto the physician role. 2) This consolidation of decision making authority onto the physician role creates operational and clinical choke points that creates delays in the delivery of care and increases the burden on all parties involved in healthcare. 3) Raising the level of sustainability of healthcare systems and improving the quality of life of care receivers, were recognised as principal motivations for ML implementation in healthcare in Japan. 4) Fourthly, the functions of ML systems in healthcare can be broadly classified as either operational or diagnostic. Furthermore, observations suggest that diagnostic functions that support or endorse nurses' conclusions and recommendations, would give nurses more confidence in dialogue with physicians. 5) Finally, an analysis of overseas solutions revealed that countries with similar societal needs have shifted to an interprofessional model that divides decision making tasks more equally between clinical roles.

Findings: These 5 themes were then utilised to derive two findings that explain current realities. 1) Existence of a global trend towards the expansion of non-physician clinician roles, and the subsequent diversification of decision making authority. 2) Innovative solutions such as machine learning functions and the diversification of decision making authority, can be combined to enhance each of their strengths.

Policy Proposals: In light of these findings, this study presents three policy proposals: i) further employment of pre-existing decision making authorities allotted to non-physician clinicians such as prescription inquiry, and an expansion of the administrative interpretation of "assistive acts" that would lead to a reconsideration of diversifying decision making authority and the eventual delegation to other professionals, ii) permitting the implementation of diagnostic machine learning systems,

which can standardise the quality of decision making and ensure a level of safety across all clinicians, and iii) delegating clinicians with new decision making authorities the right to directly bill social insurance systems for their service.

Conclusion: Ultimately, laws and policies in Japan create a steep and irreversible power gradient that consolidates decision making functions to the physician. Many of the structural chokepoints are linked to this concentration of authority, which would also prevent a maximal utilisation of diagnostic ML systems. However, a complete overhaul of the legal structure concerning healthcare will not happen overnight. Consequently, it would be more realistic to start by making the best out of pre-existing systems and ambiguities regarding the nature of "assistive acts" and focus on the diversification of decision making authority in specific fields with increasing need such as primary care and home hospitalisations. Meanwhile, the themes extracted from this study offer reasons to hope that ML could bring about a disruptive breakthrough that will greatly alter the power structure in Japanese healthcare, albeit through an increased recognition of its potential benefits not just within the circle of healthcare professionals but also amongst policy makers and the general public.

要約

背景：AI（人工知能）はヘルスケアにおける革新の起爆剤となるものとして期待されている。したがって医学への人工知能の応用研究例は数多く存在するものの、AIの看護への応用に関する研究、特に日本の看護政策への示唆に関する文献はまだ少なく、研究のニーズがあると考えられる。

目的：本研究の主たる目的は、日本の看護師の役割とそれに関連する政策に対してAIの持つ潜在的なインパクトを分析し、AIの有益なポテンシャルの具現化を妨げうる日本の医療の構造的障壁を特定することである。この研究目的を、グランデッドセオリーアプローチ(Grounded Theory Approach)に沿った複数のサンプリングプロセスに従い、研究目的を以下の3点の小目標に細分化した：

i) 人工知能（特に機械学習）がヘルスケアにおいて果たす機能の調査、ii) 日本の看護師の役割を定義づける政策と法的構造の究明、iii) 看護領域での人工知能の活用を通じて克服が期待される政策的ボトルネックの特定と、看護領域で人工知能の活用を促進する為の政策提案。

研究方法：この研究はグラウンデッドセオリーアプローチを活用し、初期優位的サンプリング・1次理論的サンプリング・2次理論的サンプリングの3層によって分析を行った。さらに各サンプリング中に抽出された新しいテーマから仮説を構築し、次のサンプリングを行った。本研究では、計210の文献、7回の個別インタビュー、およびグループインタビューを1回行った。

抽出見解：3層のサンプリングから5つの主要な見解を抽出した。
1) 医療専門職の間には異なる力関係が存在し、明文化されていないものの医療政策・法制度によって固定化されている。さらに、これらの政策や法制度は、必ずしも専門職間の業務内容を規定していないにもかかわらず、診断・意思決定権限を医師に集約するものと考えられる。
2) 診断・意思決定機能の医師への集約は、運用上・臨床上のボトルネックを引き起こす一つの要因である。これらはケア提供の遅延、医療関係者の負担増大を引き起こすと考えられる。
3) 日本のヘルスケアに機械学習システムを導入する主要な動機として、医療・保健制度のサステナビリティの向上と患者・要介護者のQOL向上の2点が挙げられる。
4) ヘルスケアへの応用に際して機械学習システムの機能は大きく「運用効率化機能」と「診断機能」に分類できる。さらにインタビューから、機械学習システムは看護師の判断や提議をサポートすることで、看護師が医師との関係においてより自信を持って接する事ができるようになる手立てとなりうると推察される。
5) 海外事例を分析したところ、同様の社会的ニーズを持つ先進国の多くは意思決定の役割をより多様化させたチーム医療モデルに移行していることが明らかになっている。

調査結果：これらの5つの見解から、2つの主な調査結果が引き出された。1) 多くの先進国では、診断・意思決定権限を持つ専門職の多様化が多くの社会的課題への解決策として活用されている。2) 機械学習システムの診断機能の効果的活用には意思決定権限の多様化を同時に行う事が合理的である。

政策提案：調査結果を元に、i)薬剤師の持つ疑義照会のように医師以外の専門職の持つ意思決定機能の更なる活用と、「診療の補助」に対する行政解釈拡大の加速化、ii)診断機能を持つ機械学習

システムの活用による意思決定の質の標準化と安全性の水準確保、iii)医師以外の専門職が行う行為に対する診療報酬加点の拡大、この3つの政策提言を行いたい。

結論：この調査を通して、日本の医療政策・法制度は医師に意思決定権限を集約し、専門職間のパワーバランスを硬直化させている事が明らかになった。また、医師への診断・意思決定機能の集中はその他多くの構造的ボトルネックの根源となっており、診断の行える機械学習システムの使用を医師に限定すれば新しい技術の革新的なインパクトを削いでしまう可能性が推測される。しかし医療政策・法制度が一晩にして変わると期待するのは現実的ではない。したがって、まずは疑義照会や、敢えて言えば「診療の補助」の曖昧さなど現行の枠組みを利用しつつ、診断・意思決定権の多様化を、プライマリケアや在宅医療のようなニーズの増加が見込まれる領域に限定する事によって図ることがより実践的だと思える。一方、機械学習の応用に関する議論がパワーバランスに変革をもたらす突破口となる可能性は大いに残されていると同時に、今後はその潜在的メリットについての認識を医療関係者の間だけでなく政策立案者や一般市民に広めていく必要がある。

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List of Abbreviations

AI: Artificial Intelligence

CT Scan: Computerised Tomography Scan

ICT: Information and Communications Technology

MHLW: The Ministry of Health, Labour and Welfare (Japan)

ML: Machine Learning

MRI: Magnetic Resonance Imaging

NP: Nurse Practitioner

RN: Registered Nurse

Part 1: Introduction

Part 1a: Background and Objectives

Healthcare as we know today is far from what existed a century ago. In fact, the history of healthcare is marked by giant leaps and transformations in practice, often accelerated by technological innovations that have placed healthcare at the forefront of applied science. Just to give a few examples, the development of antibiotics commonly associated with Alexander Fleming's discovery of Penicillium Notatum, the pacemaker invented in 1926 by two Australian scientists, the invention of the CT scanner and eventually the MRI, and the modern disposable catheter were all either discovered or invented in the past century. Each of these devices and medications have revolutionised healthcare in its own way, and it is nearly impossible for us to imagine treating patients without these appliances. Today, many researchers and clinicians hope that Artificial Intelligence would bring the next big revolution in healthcare. Consequently, there are numerous examples of AI research pertaining to its application to medicine. However, "medicine" does not incorporate healthcare in its entirety, as many non-physician clinicians collaborate with physicians in the provision of care. Moreover, there is a gap in research pertaining to the application of AI to nursing, especially in the field of nursing policy in Japan. Therefore, this study aims to investigate AI's potential impact on the role of nurses and its related policies in Japan and identify structural impediments in Japanese healthcare that could hinder the realisation of such potential benefits.

This study incorporates three main objectives. The first objective is to explore existing research and extract key themes through the investigation of emerging technologies such as AI and policies implemented in other countries or regions that could serve as potential solutions. Particularly, this paper will examine the general functions of AI as applied to healthcare, the main objectives and challenges related to its implementation, and current research pertaining to the application of AI to nursing. Secondly, this research will consider the policies and legal structures in Japan that fulfill the following categories: 1) Policies aimed at attainment of extracted objectives that could be accomplished more efficiently through the use of AI. 2) Policies and legal structures that define the role of nurses in Japan. Finally, this research will identify policy choke points that could be cleared through the application of AI in the nursing field and present policy proposals that could expedite this implementation. In order to accomplish these objectives, the study was conducted using a grounded

theory approach, beginning with an initial purposive sampling, then proceeding to multiple theoretical sampling processes. The research methodology will be elaborated further in the following section.

Part 1b: Research Design - A Grounded Theory Approach

The conceptual framework behind the research design of this study is based on the grounded theory approach. As a general research methodology, this framework involves the establishment of an open and broad question at the beginning of the study, followed by a series of sampling processes that involve continuous comparison of data and extraction of themes. Each sampling process was continued until reaching a point of "Theoretical saturation" where "no new properties, dimensions, or relationships emerge during analysis"[1]. Upon arriving at this point of theoretical saturation, key themes were identified and new hypotheses were created in preparation of a new sampling phase. The objective of a grounded theory approach is to create a theory. However, it would be helpful to note that a "theory" in this sense, could be defined as a collection of logical knowledge corresponding to everyday practice. This is in contrast to the comparatively common definition of a "theory", which is a collection of propositions utilised to illustrate principles and predict future outcomes. Therefore, this paper will utilise "finding" as the term that describes the collection of key themes.

As for this study, the research trajectory emerged in the following manner. After designating a broad research objective as mentioned in the introducion, an initial purposive sampling process was conducted. The predominant question for the initial purposive sampling process inquired about the potential impact of AI on nursing. Therefore, the focus rested on topics such as the functions of AI in healthcare, purpose of introducing AI in healthcare, and specific research examples of nursing AI. The study sustained the initial purposive sampling phase until reaching "Theoretical Saturation", then moved on to the first Theoretical sampling process. The Theoretical Sampling process examined more specific themes and objects of interest and was cyclically repeated until the emergence of specific choke points needed for policy recommendations. Expounding upon the themes and hypotheses that emerged during the initial purposive sampling, the principal question during the first theoretical sampling process was: "what factors define the role of nurses", and hence focused on the analysis of legal structures, organisational structures, policies and stakeholders. The second Theoretical Sampling process asked two principal questions: "what are some specific choke points in healthcare, especially related to governance" and "how have other countries and regions responded to similar issues and objectives observed in Japan". Consequently, the second Theoretical Sampling process involved more case studies and analyses of systems and policies overseas. In the end, the extracted themes were

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[1] Strauss, A., & Corbin, J. (1998, p. 143).

organised in layered structures of varying depths. Linkages were created between these themes and the concepts were refined to construct policy proposals.

Overview of the Literature Review

A comprehensive literature review of 210 articles and was undertaken for this literature review. These articles were discovered using Google Scholar, Pubmed, Jstor and OPAC UTokyo under the keywords: "nursing authorised acts", "nursing artificial intelligence (看護・人工知能)", "artificial intelligence nursing scope of practice", "nursing authorised acts", "nursing scope of practice ", "regional healthcare nursing(地域医療 看護)" "nurse prescribing (看護師 処方)", "registered nurse prescribers", "nursing scope of practice expansion", "medical artificial intelligence". The keywords also written in Japanese were investigated in both English and Japanese.

Overview of Interviews

Interviews were also conducted from May to October 2020 with two main objectives in mind. The first was to augment the literature review and to further extract information regarding choke points that exist within the nursing profession. The second was to gather more information from those involved in medical AI development in order to gauge the current state of research and to identify trends as to how researchers envision the application of AI in the field of healthcare. The participants of the individual interviews were from Japan, the United States and the United Kingdom. Their professions were: Registered Nurse, Nurse Practitioner, Specific Acts Nurse (特定看護師), University Faculty, Physician, Nursing researcher, and Public Health researcher (All of the participants corresponded to more than one of these roles). The group interview was held on 7 August, 2020. The group interview consisted of two Specific Acts Nurses and one Public Health researcher.

Part 1c: Organisational structure of this paper

This paper has been organised in a layered structure that reflects the sampling processes that follow the grounded theory approach. Hence, the sections of this paper will elaborate upon sampling processes in the order of completion, starting from the investigation of broad themes in Part 2 and ending with the investigation of specific themes as well as the plausibility of certain policy suggestions in Parts 4 and 5. Moreover, parts 2 through 4 of this paper each illustrate a subsequently deeper sampling process, ending with a summary of findings and a generation of new research questions that lead to the following layer of sampling (in exception of Part 4, which leads to the discussion and conclusion rather than another sampling process. This was because the findings

extracted from the second theoretical sampling process covered in Part 4, was sufficiently conducive to the formulation of policy suggestions).

To describe each section in further detail, Part 2 illustrates the initial purposive sampling process which aimed to extract broad themes related to the question "What can AI systems do in healthcare". This is due to the fact that this research project was initiated with the aim of discovering the impact of AI and particularly, ML systems in the realm of nursing in Japan. Hence, Part 2 answers general questions regarding the general functions of AI, the objectives of its implementation in healthcare and in particular, its envisioned application in nursing. Part 3 describes Theoretical Sampling 1, which further investigated the themes and hypotheses that emerged during the initial purposive sampling. The aim of this sampling process was to uncover the various factors defining the role of nurses', and hence focused on the analysis of legal structures, organisational structures, policies and stakeholders. Expounding upon these findings, Part 4 illustrates Theoretical Sampling 2, answering two principal questions: "what are some specific choke points in healthcare, especially related to governance" and "how have other countries and regions responded to similar issues and objectives observed in Japan". Consequently, Part 4 includes case studies, analyses of systems and policies overseas, and provides an outlook on new nursing roles that are emerging in the realm of home care. Finally, Part 5 concludes the paper with a summary of major themes, policy suggestions, and questions that have been left for further investigation.

Part 2: Initial Purposive Sampling - "What can AI systems do in healthcare?"

2a Extraction of themes

One could perhaps say that two of the most important factors that have driven changes in healthcare are the evolution of technology, and adaptation to societal needs. Today, AI and more specifically, ML is the most prominent example of the former, while the latter factor consists of many subcomponents that range from 1) rising healthcare costs and 2) the lack of healthcare personnel, to 3) alterations in the policies that regulate the field. Hence, it is to no surprise that one can easily find an abundance of literature pertaining to the application of AI to healthcare, and various strategies that respond to these societal needs such as the liberalisation of nurses' role and SoP, which has recently become a global trend. However, the literature addressing the effect of AI technology in transforming nurses' roles was found to be very sparse, and a particular research gap was identified in the area concerning the alteration of the legal and organisational structures that are necessary for the coordination of these transformations that would allow AI to be utilised at its fullest potential. To begin, this section will provide a initial purposive sample of each of these subcomponents: the general functions of AI as applied to healthcare, the societal objectives of its implementation, and the implementation of AI technology envisioned in the field of nursing, in order to illustrate the backdrop on which ML is making an entrance today.

2ai: The general functions of Artificial Intelligence

Many policymakers and healthcare professionals alike are very excited about the application of "AI", as expressed in a formal statement issued by the Cabinet Office of Japan regarding what they dub "Society 5.0"[2]. However, not all stakeholders have a good grasp on the impact of AI and ML, on healthcare. This section will briefly summarise the basic function and the potential benefits that could be realised along with the implementation of ML technology.

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[2] Cabinet Office. (n.d.).

Defining Key Concepts

When "AI technologies" are mentioned in the news nowadays, it is often used in tandem with other buzzwords such as "ICT", "Big Data", ML and deep learning. Hence this section will begin by defining key concepts.

First of all, "Artificial Intelligence" is defined as "the capability of a machine to imitate intelligent human behavior"[3] or more comprehensively as "the study of how to produce machines that have some of the qualities that the human mind has, such as the ability to understand language, recognize pictures, solve problems, and learn"[4]. Nonetheless, "Artificial Intelligence" is merely an umbrella term that encompasses a whole variety of research.

Next, ML is described as the *ability for a computer to learn without explicit programming*[5], in the field of computer science where this concept was first developed. Simply put, ML systems can make decisions and predictions autonomously from inferences derived from patterns of data, instead of specific instructions that have been required for the operation of conventional computers. Consequently, a major strength lies in its ability to extract patterns from non-linear patterns within data. Within the subcategory of ML in the field of AI, there are several varieties of ML models. These models include genetic algorithms, bayesian networks, regression analysis, support vector machines, decision trees, and artificial neural networks[6].

Another key term frequently used interchangeably or simultaneously with AI, is Deep learning. Deep learning is a variety of ML models that creates artificial neural networks that consist of multiple layers. Hence, deep learning derives its name from the depth created by these multi-layered structures. In contrast to deep learning, standard neural networks consisting of a few layers have existed for decades. Fundamentally, both standard neural networks and deep learning networks function largely in a similar manner, consisting of many simple connected processors that produce a sequence of real valued activations[7]. By adjusting the appropriate triggering weights of input for these neurons, neural networks can learn to exhibit a desired behaviour in response to a certain input. Depending on how these weighted neurons are connected in the system, the input of behaviour could require long chains of computational stages. Each of these stages will affect and transform the accumulated response of the network. Deep learning has been considered revolutionary in the way it has been able to

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[3] Artificial Intelligence. (n.d.). In *Merriam-Webster Dictionary*.
[4] Artificial Intelligence. (n.d.). In *Cambridge Dictionary*.
[5] Samuel, A. L. (1988).
[6] Jeong, G. H. (2020).
[7] Schmidhuber, J. (2015).

accurately assign neurons' triggering weights over many stages[8]. As a result of this technology, deep learning networks have become able to extract patterns out of unstandardised data and demonstrate complex behaviours in response.

To give an example of a key application area, research pertaining to autonomous driving has accelerated significantly due to deep learning. On one hand, conventional computer programmes have been utilised for vehicles that operate in very predictable environments. Modes of transportation such as aviation and railroads have both implemented variations of auto-pilot systems to assist operators. However as previously mentioned, these programmes can only operate in very predictable situations, as its response to an unexpected situation is often limited to its ability to alert the operator. On the other hand, deep learning systems have now given researchers the capacity to experiment with cars that gather complex input from a vast array of sensors including cameras and radars, while simultaneously exhibiting an autonomous response best suited to each situation. When applying the analogy to the realm of healthcare, one could say that day-to-day operations are much like driving compared to riding on railway tracks where one can easily observe a destined path. It is exactly this potential to recognise patterns from complex input and respond autonomously, that is expected to change healthcare and the role of practitioners like never before.

Key Examples of AI systems in clinical settings

This section will introduce a few key approaches to the implementation of AI in the clinical situation, in order to demonstrate the rationale behind this generalisation. These commonly used approaches will be described in the order of image processing, natural language processing, and integration with data collection devices.

Image Processing

Firstly, image processing is perhaps the most celebrated approach to utilising ML, out of all others. In particular, many researchers and clinicians alike hope that AI can revolutionise the processes that lead to more efficient and accurate tumour region identification, prognosis prediction, tumour microenvironment characterisation, and metastasis detection[9]. One such example of this approach is found in lung cancer pathology image analysis. Researchers from India used CT scans from the Lung Image Database Consortium as input for the convolution neural network, to determine whether the network can learn from the images to predict whether a particular lung is either normal, has a benign tumour or a malignant tumour. In order to facilitate the learning process of the neural network, the

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[8] Schmidhuber, J. (2015).
[9] Wang, S., Yang, D. M., Rong, R., Zhan, X., Fujimoto, J., Liu, H., . . . Xiao, G. (2019).

RGB interpretation of the CT scans were converted into monochrome, then further converted into a binary image. Results showed a cumulative accuracy of 94.34% from the proposed system[10].

Another example pertains to the utilisation of pathology images for the prediction of one's response to various treatments. Wang et al. have been able to develop convoluted neural network models to classify histomorphometric image patches into categories such as orientation, texture, shape, and tumour architecture in order to predict disease recurrence in early stages of non-small cell lung cancer [11]. Additionally, Wang et al. has also applied convoluted neural networks to images in order to further extract tumour boundaries and shape features. The deep learning network in turn, was able to use this information to provide a prognosis for lung adenocarcinoma survival. In a similar type of research, Saltz et al. have been able to learn more about the spatial organisation and molecular correlation of lymphocytes using deep learning algorithms and utilise this data as a prognostic element of lung cancer[12]. While physicians have traditionally relied heavily on visual information to diagnose diseases, many pathologies are indeed difficult to recognise even for experienced physicians. As image processing is an undeniable strength of ML, such functions are likely to develop as decision support tools in the near future.

Natural Language processing

Next, natural language processing is another key approach that could have a large impact on clinicians' practice. Yang et al. for example, developed a natural language processing system that identifies relations of medications with adverse drug events, using a convolutional neural network to analyse 505 clinical notes with identifications removed[13]. This ML system has many implications for clinicians, due to its ability to extract meaningful relations from natural clinical narratives instead of pre-prepared data sets. Natural language processing systems have the potential not only to prevent adverse pharmaceutical reactions, but the potential to be expanded even further to function as a tool that can increase clinician efficiency by streamlining tasks. An example of this type of implementation is seen in a research project conducted by Tsuru et al. from the University of Tokyo. Between May to August 2019, Tsuru used a patient condition adaptive path system in order to summarise information noted in clinical progress sheets, and link the extracted information to electronic medical records. The objective of this study was to understand and improve record-keeping processes by nurses, and to share the observations with physicians in a smooth manner. Though the information of approximately 4000 patients was extracted and analysed using this system over a four

[10] Bhalerao, R. Y., Jani, H. P., Gaitonde, R. K., & Raut, V. (2019).
[11] Wang, X., Janowczyk, A., Zhou, Y., Thawani, R., Fu, P., Schalper, K., . . . Madabhushi, A. (2017).
[12] Saltz, J., Gupta, R., Hou, L., Kurc, T., Singh, P., Nguyen, V., . . . Van Arnam, J. (2018).
[13] Yang, X., Bian, J., Fang, R., Bjarnadottir, R. I., Hogan, W. R., & Wu, Y. (2019).

month period, major problems have not been observed[14]. This shows that natural language processing functions can easily adapt for diagnostic purposes and for the augmentation of operational effectiveness.

Utilisation of other data collection tools

Finally, ML algorithms are often used in tandem with data collecting tools such as surveys, sensors, wearable devices. Ladstätter et al. for example, investigated whether neural network paradigms offer better predictions of nursing burnout from 'Nursing Burnout Scale' surveys, compared to predictions made by statistical methodologies. The outcomes showed that the relationship between burnout and predictive variables such as age, job status, workload, experiences with pain and death, interactions involving conflict, role ambiguity and hardy personality is not entirely linear. The outcomes also justified the use of neural networks to predict burnout, due to neural networks' superior ability to extract patterns from non-linear relationships[15].

While Ladstätter et al. utilised survey results, Inoue employed accelerometers in smartphones in order to train a ML system to learn to recognise different actions being undertaken by nurses[16]. This kind of "action-tracking" system could improve operational effectiveness through the identification of time consuming tasks that serve as operational choke points and improved planning for future events. Google Health also takes a similar approach of linking wearable devices to AI systems in order to create a platform for more personalised care. Their acquisition of fitbit as well as their merger with Deepmind, a UK based AI developer[17], could be a sign of their intent not just to integrate ML with hardware design, but to make medical AI available to both clinicians as well as the general public.

Seven examples of ML research were presented, excluding the closing statement about Google Health. As shown above, there are numerous individual objectives of the implementation of AI technologies to the realm of healthcare. These specific objectives include lowering costs, reducing the workload for physicians, streamlining care, preventing illness and injury, the creation of new remedies to illness, the identification of risk factors, creating linkages with wearable devices, and more accurate diagnoses.

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[14] Tsuru, S., Tamamoto, T., Furuya, H., Nakao, A., Fukuyama, M., Tanizaki, K., & Yahagi, N. (2020).
[15] Ladstätter, F., Garrosa, E., Badea, C., & Moreno, B. (2010).
[16] Inoue, S., Lago, P., Hossain, T., Mairittha, T., & Mairittha, N. (2019).
[17] DeepMind. (2018, November 13). *Scaling Streams with Google* [Press release].

2aii: The objectives of implementing AI in healthcare

To provide a framework to understand the main objectives of the implementation of ML in healthcare, this paper broadly classifies the function of ML as operational or diagnostic, according to its function. On one hand, the identification of tumours from a CT scan would be categorised as a diagnostic function. Similarly, the determination of lung cancer prognosis from image data would also be considered a diagnostic function. On the other hand, the extraction of key information from clinical progress sheets and its automatic reflection on the communiqué between nurses and physicians, would be seen as an operational function that increases the level of efficiency. Additionally, the action-tracking system would also be considered an operational function, as it does not make direct clinical impact but rather has the potential to reduce the clinicians' workload through better allocation of time for various tasks. Diagnostic functions are linked to decisions that directly affect the patient's care plan, while operational functions increase the level of efficiency or efficacy of a predetermined care plan. To summarise using an allegory, diagnostic functions can be likened to tools that help engineers lay a new path or make alterations to its route, while operational functions resemble traffic lanes and lights that ensure safe and efficient travel.

Furthermore, it would be important to note that diagnostic functions are not always linked to the image processing approach of ML, nor do other approaches such as natural language processing contribute solely to the augmentation of operational functions. A counter example of this would be the prediction of acute kidney injury using algorithms to extract patterns from depersonalised medical records. This is to say that each of the major functions of ML algorithms (image processing, natural language processing, integration of data collection devices), could serve both operational purposes as well as diagnostic purposes. These concepts will be elaborated further in the following sections.

A Classification of ML into Diagnostic and Operational Functions

This next section will further elaborate on the broad classification of ML as applied to healthcare into the *diagnostic* function and *operational* function, providing examples of each.

As mentioned previously, ML is envisioned as a *Diagnostic* or *Prediction Making* tool. In other words, it will assist or perhaps eventually assume the diagnostic task, since the true value of ML lies in its capacity to extract novel insights from exceptionally large samples of data. To give an example, a double-blind study comparing the decisions made by the Watson Oncology system and the tumour board showed a concordance of 90%, with the system only requiring 40 seconds to complete the

process[18]. A novel AI clinical support system that could produce a diagnosis and options for medical treatment for peripheral neuropathies showed 93.3% accuracy compared to experts' opinions, and an Early Detection and Prevention System developed as early as 1998 to provide recommendations and guidance for Nurses or paramedical personnel showed 94% consistency with physicians opinions[19]. These exceptionally accurate systems provide solutions for primary care patients who do not have easy access to specialists, hence providing a way to bypass the shortage of medical practitioners in primary care, a major choke point in contemporary healthcare.

ML is also expected to streamline operational tasks such as generating, storing and retrieving medical records[20]. As mentioned before, Nurses in the medical-surgical areas spend a large portion of their time to document, administer medication, and coordinate care. This significantly reduces the amount of time that Nurses spend with the patient or on tasks that require critical thinking. Improvements in Natural Language Processing could potentially reduce the amount of time required for documentation, as well as for the identification of pertinent data from the plethora of charted information.

Improvements in mobile health applications and wearable devices help ML algorithms achieve precision in information gathering. A growing number of these applications and devices allow patients to track and monitor their own health status, including blood glucose levels, blood pressure, and levels of physical activity. As chronic conditions have become the main focus of healthcare systems in advanced countries, home monitoring could enhance more accurate data collection and comprehensive care management. For example, a multicentre study of ambulatory hypertension monitors found that ambulatory tracking was safer as well as more accurate than the readings at doctors' offices, as values are not affected by what is commonly known as "white-coat hypertension" [21]. Not only does this notion challenge the traditional assumption that physicians are necessary to gather health information, but it also indicates capacity for real-time monitoring would also reduce costs that are linked to unnecessary appointments.

Medical (Diagnostic) AI classified by its capacity for autonomous practice

In response to the growing number of healthcare professionals and policy makers interested in seeing ML benefit healthcare in various ways, researchers in Japan have proposed a type classification for medical AI systems in order to help build trust between users (physicians, engineers, patient and related stakeholders) and AI systems, while also highlighting specific policy related challenges. This

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[18] Guo, J., & Li, B. (2018).
[19] Guo, J., & Li, B. (2018).
[20] Shaw, J., Rudzicz, F., Jamieson, T., & Goldfarb, A. (2019).
[21] Bauer, L., & Bodenheimer, T. (2017).

project proposed 6 categories of medical AI (types A through F), each classified by technical capacities of AI systems, its potential impact on health care professionals and patients, as well as requirements for engineers as they apply this technology for clinical use. To give an example of these definitions, medical AI type A has been classified as "an autotext system that supports the acquisition and input of patient information, contributing to clinical support"[22] which eliminates the need for obtaining and entering patient information. Type B is considered a secondary clinical support system where physicians can provide medical care with support from the AI system. The key difference between Types B and C is that while physicians are expected to analyse first in Type B, machines complete initial analysis in Type C. Therefore, in Types C and beyond, the initial use of AI analysis results will reduce the burden on physicians' time and resources for interpretation. Types A through C are considered preliminary substeps that encompass clinical support, while types D through F classify AI systems that could accomplish clinical automation, requiring minimum assistance from physicians. Taking into account these type classifications as summarised in the chart inserted below, the author would like to note that the policy suggestions were envisioned with types B through D in mind. Therefore, while it would be pertinent to begin considering the various policy possibilities today, these policies will not come into effect until the emergence of such technologies, perhaps 10 to 15 years into the future.

	MA Types	Technical requirements to engineers (Including Accuracy, User Interface)	Potential impact on health care professionals (Including use and institutional design)	Potential impact on the patient
Clinical Support: Sub-step	**Type A: AutoText** The AI system supports the acquisition and input of patient information that contributes to medical care support	• A user interface that can be input electronically to facilitate information processing	• Reduce physicians' burden of obtaining and entering patient information • Data management and interpretation issues may arise	• IT literacy is required to patients, such as entering information electronically instead of asking questions • It can reduce latency
	Type B: Secondary medical support Physicians provide medical care with AI system support	• AI systems are accurate enough to support medical care • A user interface is needed that allows physicians to make and interpret decisions and interpretations independent of the AI system.	• Although it does not directly reduce the burden on physicians, secondary information presentation is expected to improve the quality of medical care by preventing oversights and ensuring uniformity of quality • It can be used as an alternative to double-checking by physicians • It may affect the judgment of the treating physicians	• Improve the quality of inspections by preventing oversights • Access to the same quality of care at all medical institutions (Uniform Quality of Medical Care)
	Type C: Primary medical support Physicians perform medical activities based on AI system support	• AI systems can support medical care with the same level of accuracy as physicians with mature knowledge in the field • A user interface is needed to guide and navigate physician inquiries, tests, and diagnoses.	• Initial use of AI analysis results reduce the burden on physicians, time and resources to interpret • It is expected to equalize the quality of medical care • It can be used as an alternative to double-checking by physicians • It may affect the judgment of the treating physicians	• Improve the quality of inspections by preventing oversights • Access to the same quality of care at all medical institutions (Uniform Quality of Medical Care)

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[22] Ema, A., Nagakura, K., & Fujita, T. (2020, p. 253).

Clinical automation: Steps			
Type D: Advanced medical support Physicians who do not have mature knowledge in the field perform medical activities based on AI system support	• AI systems can support medical care with the same level of accuracy as physicians with mature knowledge in the field • A user interface is needed to guide and navigate physicians who do not specialize in the field inquiries, tests, and diagnoses.	• Initial use of AI analysis results reduce the burden on physicians, time and resources to interpret • It is expected to equalize the quality of medical care • It will be possible to provide medical care in areas where there are no available specialists in the field	• Improve the quality of inspections by preventing oversights • Access to the same quality of care at all medical institutions (Uniform Quality of Medical Care) • Better access to specialized care
Type E: Fully automated medical care (mediated by medical staff) The AI system provides medical care, and presents diagnostic results and prescriptions to users and non-physicians	• AI systems can support medical care with the same level of accuracy as physicians with mature knowledge in the field • A user interface is needed that guides and navigates users to interview, examine, and diagnose problems in specific locations (e.g. pharmacies, opticians).	• The physician is absent • A legal and social system to enable the automation of medical care is necessary	• More options for a place where medical care is available
Type F: Fully automated medical care (no intervention by medical staff) The AI system provides medical treatment, and presents the results of the diagnosis and prescriptions to the user	• AI systems can support medical care with the same level of accuracy as physicians with mature knowledge in the field • A user interface is needed that guides and navigates users everywhere to interview, examine, and diagnose themselves. • Can be used in app	• The physician is absent • A legal and social system to enable the automation of medical care is necessary	• More options for a place where medical care is available

(From: Proposal for Type Classification for Building Trust in Medical AI Systems[23])

While many AI specialists agree that ML will primarily serve to augment and not replace the role of humans in healthcare in the near future[24] since the current role of ML functions at the level of the "task" as opposed to the "entire job"[25], it will undoubtedly play a transformative role. While AI cannot replace human empathy and communication, it has the ability to catch up with the ever growing pool of medical research which would require caregivers to read 29 hours per workday if he/she would like to stay completely up to date[26].

AI can be applied to healthcare in a multitude of ways, and the vast variety of research in this field accurately conveys its breadth. As mentioned previously, some of the most well known applications of AI occupy the field of visual information, such as the analysis and diagnosis of lung cancer from images. The potential for risk assessment and the production of prophylactic information derived from past health history and family history, are also amongst other clinical applications of AI technologies. Additionally, other branches of research are concerned with more operational functions. Some of the tools currently being developed include AI systems that can create medical charts from audio data, visual recognition functions that can not only understand handwritten charting data but also decipher complicated medical lexicology, as well as systems that help nurses schedule their tasks in the most effective manner.

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[23] Ema, A., Nagakura, K., & Fujita, T. (2020, p. 253).
[24] O'brien, E., White, W. B., Parati, G., & Dolan, E. (2018).
[25] Shaw, J., Rudzicz, F., Jamieson, T., & Goldfarb, A. (2019).
[26] Guo, J., & Li, B. (2018).

Placed in more generalised terms, the application of AI to medical institutions mainly concerns itself with data collection and analysis, but at a speed far greater than that which can be processed by a human being and a level of accuracy comparable to that of a licensed professional. Additionally, AI technologies should be implemented conjointly with information and communication technologies or ICT that allow for more streamlined data sharing. There is good reason to believe that these functions can resolve some of the choke points that prevent healthcare systems from achieving its full potential, while also accelerating the transition from care centered around acute care to chronic illness management.

Current societal needs that pertain to ML in Healthcare

Since the previous section elaborated upon the functions of AI as well as some of its specific applications, this section will present an overview of the societal needs confronting healthcare systems. The aim of this section is to demonstrate a link between the functions of diagnostic and operational ML systems, and the societal needs that could be fulfilled as a result of its application. The general areas of need will be discussed in the following order of 1) a rise in healthcare costs, 2) the lack of healthcare personnel and overworked healthcare staff, 3) the lack of efficiency due to rigid infrastructure, 4) and the need for more comprehensive chronic illness management. These general areas of need can be generalised as issues that have the potential to compromise the sustainability of healthcare systems, and issues pertaining to the shift from a focus on curing the patient to caring holistically for the patient.

Rise in healthcare costs across developed countries and regions

Firstly, the current rise observed in healthcare costs poses a tremendous threat not just for Japan, but also for many developed countries. For example, the provisions of the "Patient Protection and Affordable Care Act" in the United States greatly extended the coverage of "Medicaid" into the realm of primary care, increasing the proportion of the burden that must be borne by the government [27]. In Japan, projections estimate a rapid increase in health insurance costs due to the ageing demographic composition, especially since elderly people not only utilise healthcare services more frequently, but also for a prolonged duration as the focus of healthcare shifts from treating infections to chronic disease. To complicate this situation, Japan must also overcome "issue 2025", which outlines the dynamic shift required of the care delivery system as the entire cohort of "baby-boomers" in Japan will surpass the age of 75 in the year 2025[28].This is a critical issue, considering that medical and nursing care cost already amount to 53-trillion yen or 10% of the nation's real GDP, and the ratio is

[27] Xue, Y., Ye, Z., Brewer, C., & Spetz, J. (2016).
[28] Ministry of Health, Labour and Welfare. (2019).

expected to enlarge even further[29]. Additionally, the development and usage of new but costly technology such as CT, MRI, and PET scans as well as new patented medication, consequently expands the healthcare bill despite being ultimately beneficial and necessary in modern healthcare. Hence, the rise in healthcare costs could be disentangled further in attribution to four respective elements, A) an increase in population in certain societies, B) increased population senescence, C) an alteration of disease structures and finally D) the complexification of medical treatments.

Lack of healthcare workers and overwork in Japan

Secondly, many developed and developing countries are being strained due to their lack of healthcare personnel, especially in key sectors such as primary care or rural areas. Once again, this central issue can be divided into different subcomponents.

A) Physicians around the world have increasingly chosen to specialise over working in primary care[30]. This has caused systemic burnout, forcing other healthcare workers such as Nurses to assume roles that have traditionally been held by Physicians. There has also been a trend of experienced yet overburdened Physicians who adhere to a University hospital network, increasingly deciding to open a private clinic in specialisations that are less risky. This trend has been named "Drift-away Sabotage (立ち去り型サボタージュ)" as it precipitates the cavitation of advanced healthcare particularly in rural regions[31].

B) To exacerbate the problem, rural areas in both developed and developing countries have seen a comprehensive shortage of healthcare professionals including nurses, as is the case in South Africa. Not only are the nurses in these regions overburdened, they do not have the chance to receive continuous education that prepares them for chronic disease management and unforeseen challenges.

C) Furthermore, studies have revealed that many Nurses allocate a significant amount of their time on tasks such as documentation and the administration of medication[32]. These activities deduct valuable segments of time that could be spent on tasks that require critical thinking and empathy.

In Japan, the reduction of physicians' overtime work has been identified as an urgent need by the MHLW. In an effort to mark a clear standard to which employers can adhere, the Japanese government has set a standard of 80 hours of overtime labour per month as the "death from overwork

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[29] Ema, A., Nagakura, K., & Fujita, T. (2020).
[30] Maier, C. B., & Aiken, L. H. (2016).
[31] Shimada, T. (2017).
[32] Dufour, B. (2018).

line (過労死ライン)"[33]. Alternatively described, any amount of overtime labour over 80 hours per month has been determined as a significant risk factor of death, and employers are strongly encouraged to limit the amount of overtime work to prevent surpassing this standard. Meanwhile, research conducted by the MHLW has also shown that 40.5% of physicians working in hospitals surpass the standard of 80 hours of overtime work per month[34]. In fact, 22.1% of all physicians working in hospitals were found to be recording over 120 hours of overtime work per month, with 10.5% even completing over 160 hours. In response to this situation, the MHLW has implemented a comprehensive plan to limit the maximum amount of overtime work to 80 hours per month by April of 2024, and to place a penalty on healthcare institutions that cannot meet this standard, unless the physician is serving in inescapable situations such as an emergency, or in remote regions with a considerable lack of healthcare professionals[35].

Though physicians have been the main figures under the spotlight, overwork has also been an issue for other healthcare professionals, with recent trends showing that working conditions have further deteriorated for nurses working in Japan. In particular, the working conditions of younger nurses are disproportionately unfavourable. For example in the prefecture of Okinawa, 4.6% of nurses have registered overtime labour hours that surpass the "death from overwork line". However 12.4% of first year nurses, or nearly three times the prefectural average have registered working hours surpassing this line[36]. Additionally, many nurses have not been able to register their overtime work, due to various reasons. Notably, nurses have noted significant contributions in "pre-shift labour", or uncompensated procedures that must be completed before one's shift. According to an article from the *Lancet* by Aiken et al. from 2014 comparing hospital mortality of 422,730 patients in nine european countries, an increase in a nurse's workload was shown to be a clear factor that adversely affects patient outcomes[37].

Inflexibility of healthcare policies in Japan

Thirdly, in light of these alterations in the demographic structure and corresponding societal needs, healthcare policies have remained relatively rigid and idle in helping medical institutions adopt new technologies and achieve a certain level of adaptation. Certainly, there are reasons as to why modifications have been slow to come. As mentioned earlier, Japanese society is confronted with

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[33] 脳血管疾患及び虚血性心疾患等（負傷に起因するものを除く。）の認定基準について (Issue brief No. 改正基発0821第3号). (2020). Tokyo, Japan: 厚生労働省労働基準局長.
[34] 時間外労働規制のあり方について③ （議論のための参考資料） (Publication). (2019). Tokyo, Japan: Ministry of Health, Labour and Welfare.
[35] 時間外労働規制のあり方について③ （議論のための参考資料） (Publication). (2019). Tokyo, Japan: Ministry of Health, Labour and Welfare.
[36] Sato, N. (2015).
[37] Aiken, L. H., Sloane, D. M., Bruyneel, L., Heede, K. V., Griffiths, P., Busse, R., . . . Sermeus, W. (2014).

several large societal issues that directly affect medical institutions and the national healthcare system as a whole. One prominent issue is undoubtedly the increasingly ageing population, which correspondingly augments the number of patient visits as well as the proportion of patients who require more complex procedures and medications, which in Japan are subsidised by up to 90% by the government if the patient is 75 years old or older. The lack of accessibility to healthcare is also an outstanding issue in pediatrics, obstetrics and gynecology, and across all disciplines in remote areas[38]. This issue is further compounded by the fact that the healthcare system in Japan is heavily centralised around the physician, with other healthcare professionals with limited decision making authority. This implies that many if not most procedures and processes must be initiated by a physician. Additionally, any alterations to the care plan or the prescription must also be authorised by a physician, which causes delays in the delivery of care and in turn, reduces the level of accessibility. These policies and choke points will be further elaborated in the latter part of this work. Therefore, one can conclude that the undeniable issue of overtime work compounded by the fundamental lack of healthcare professionals and operational choke points rooted in the physician-centred system will not only diminish the level of accessibility but could also prove to be a considerable threat to the sustainability of healthcare itself.

A shift from single-factored acute care to multi-factored chronic care

Finally, there is a need in Japan for a holistic chronic illness management scheme. In particular, policy makers and clinicians alike have recognised that health concerns have gradually shifted from curing acute disease to maintaining functionalities while living with chronic disease. As a premise, it is clear that the demographic structure in Japan is undergoing a shift from being an aged society to an ultra-aged society. Notably, the average lifespan in Japan is 87.05 years for females and close to 80.79 years for males as of 2015, while "healthy life expectancy" as determined by the MHLW is 71.19 years and 74.21 years for males and females respectively [39]. A quick subtraction reveals that elderly males and females in Japan spend about 9 years and 13 years respectively, with certain limitations in functions required for daily life. Furthermore, a deeper look into historical data reveals that the causes of death and illness have shifted from infectious disease such as tuberculosis and gastritis, to those that are chronic and often linked to lifestyle patterns. These new illnesses include cancer, cardiovascular disease, brain hemorrhages, and dementia[40]. However, the healthcare system in Japan has still remained largely geared towards the treatment of acute illness, most appropriately expressed in the number of hospital beds (13.1 per 1000 residents as of 2019) which is significantly higher than

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[38] Ministry of Health, Labour and Welfare. (2019, p. 370).
[39] Ministry of Health, Labour and Welfare. (2017).
[40] Fushimi, K. (2019).

the G7 average of 5.44 per 1000[41]. In response to this shift, the government of Japan has implemented a new model of chronic care management called "home health care". While the number of medical institutions that provide home health care have increased, illness management as a whole has continued to depend heavily on models geared towards acute care. This can also be observed from data obtained in 2014, which shows that 77.3% of all deaths in Japan occur in medical institutions[42] despite many elderly persons desiring to spend their last days at home. Healthcare policies must therefore be envisioned in a manner that cultivates the possibility of more personalised care that adapts to the changing demands and limitations of elderly life.

In order to address the needs of an ageing population and sustain healthcare systems for the coming generations, the healthcare policies needed today are the ones that fundamentally accelerate the shift from acute care to chronic management in Japan, all the while preventing a substantial increase in healthcare costs and promoting a healthy working environment for healthcare professionals. Fortunately, new developments in AI technologies could provide a potential resolution, if implemented in a timely manner.

2aiii: How is the implementation of AI technology envisioned in the field of nursing?

In section 2ai, the general functions of AI, notably ML algorithms were discussed. This following section will take a closer look at the specific applications of ML technologies in the field of nursing. The following methodology was employed for the selection of research topics. Firstly, the category of AI technology was limited to ML. Secondly, this review only included ML systems intended for direct use by nurses. Thirdly, the publication date was limited to the past 10 years (2010-2020). Additionally, only one research project was included per researcher, in order to prevent double counting similar research themes. Finally, the review only included articles directly published by the developer, and no review articles were included. An examination yielded 13 results from Austria, England, France, Japan, Scotland, South Korea, Taiwan, and the United States, published during the 10 year period of 2010 from 2020. Readers can refer to the appendix entitled: "Key Nursing AI Research 2010-20" on page 81 for a brief summary of these research projects.

These 13 examples were then classified into the aforementioned categories for having either an operational or diagnostic function. These ML systems were classified as diagnostic if they included key themes such as decision making, decision support or prediction, and those decisions had a direct

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[41] Maeda, Y. (2019).
[42] Ministry of Health, Labour and Welfare. (2017).

effect on determining the course of treatment. Out of the 13 articles studied, 5 of the research projects (Finlay, Liao, Ohura, Son, Song) were classified as pertaining to diagnostic ML systems, while 8 (Barrera, Hunter, Inoue, Ladstätter, Minivielle, Miyawaki, Tsuru, Urashima) were classified as operational ML systems. Furthermore, out of the research examples from Japan, only one could be classified as an application of diagnostic functions.

2b: Generation of observations 1

Taking into account the findings from the initial literature review, this paper presents two observations and a new research question that will guide the remaining sections of the research. These two observations are summarised as follows:

Observation 1a: The creation of sustainable healthcare and the augmentation of care receivers' QoL are the two broad objectives of the implementation of ML

Observation 1b: Diagnostic functions have a potential for more transformative impact compared to operational functions.

2bi: Two Broad Objectives of ML implementation in healthcare

Observation 1a: The creation of sustainable healthcare and the augmentation of care receivers' QoL are the two broad objectives of the implementation of ML.

As previously outlined in section 2aiii, there are many urgent needs confronting healthcare, for which ML algorithms have the potential to provide solutions. Out of these needs, some directly affect the sustainability of an effective and affordable healthcare system. For example, the need for more mutual communication, telehealth, preventing a dramatic rise in healthcare costs while engaging with the complex challenges of ageing society, the lack of healthcare personnel and subsequent overwork are all issues that threaten the sustainability of healthcare.

Meanwhile, the quality of healthcare has recently become a very important issue not only for patients but also for clinicians and policymakers. This has especially been the case, considering the shift from acute care to chronic illness management, and the corresponding shift from ensuring the presence of care to ensuring the provision of quality care. Unlike many areas of acute care where one can rely on a typical regimen, chronic illness management requires a nuanced approach that considers the specific combination of not just the various illnesses and its treatments, but also factors such as age, gender,

ethnicity, occupation, living environment, family structure and socio-economic status. Consequently, clinicians and policy makers must devise methods to ensure quality care, despite the locus of treatment moving from regulated areas such as healthcare institutions, to places where variables cannot be controlled. In response to this shift, many people expect the advancement of ML technology to fill the gap through its ability to link data from various sensors and draw conclusions from non-linear data.

To summarise, this paper presents the finding that *The main objectives of the implementation of AI could be broadly defined as: developing a sustainable healthcare system, and improving the QoL of care receivers.*

2bii: Larger impact of Diagnostic functions compared to Operational Functions

Observation 1b: Diagnostic functions have a potential for more transformative impact compared to operational functions.

Next, when considering operational functions and diagnostic functions, one could conclude that these functions both ultimately lead to operational efficiency. However, while operational functions are merely extensions of ICT implementation that is linked to the acceleration of pre-existing tasks, the diagnostic functions are the main factors that can truly revolutionise healthcare.

To give an example, when diagnostic ML tools are well integrated with nurse-led inner-city or non-urban primary care clinics, a large portion of underserved populations will benefit from improved access to care. Patients would also benefit from a streamlined process, without having to make rounds between different clinics and hospitals if diagnoses can be produced by these tools then confirmed by qualified healthcare professionals. Additionally, physicians and nurses would also profit from a relief from the current lack of healthcare personnel, with the opportunity to spend more time communicating with patients. Finally, a few of the many economic benefits include a reduction of medication costs due to precise prescribing (including the act of deprescribing to prevent harmful polypharmacy), a reduction of treatment costs linked to late detections, and most importantly the proactive utilisation of non-medical healthcare personnel through the transfer of simpler medical tasks that can be accomplished in conjunction with diagnostic tools.

Hence this observation can be summarised in saying that operational functions are an extension of ICT implementation, streamlining care and removing inefficiencies. The diagnostic functions of AI are

the main factors that have the potential to revolutionise healthcare, through the clinical decision making functions currently reserved solely for physicians.

Meanwhile it would also be important to note that certain ML systems cannot be easily classified into one of these two categories. For example, an ophthalmology clinic in Himeji, Hyogo prefecture has been developing an AI system called "Deep Safety"[43]. The objective of this project is to eliminate human error in ophthalmology surgeries through accurate personal identification and the identification of the correct eye on which one should operate. A database keeps track of operational status in real time and presents identifiers that can be accessed in all examination rooms. These functions are of paramount importance since ophthalmology surgeries often render patient identification difficult due to limited skin exposure. In order to assist the surgeon, important contents such as the procedures during operation, current retinal condition, the visibility of the crystalline lens and facial photographs of the patient are provided by the system.

On one hand, it might seem appropriate to classify Deep Safety as an operational system, since its main objective is to reduce recognition errors by the means of reminding the surgeon and other clinicians involved in the operation. However, since the system also provides the surgeon with information regarding retinal condition, its function could very well serve to alter surgical procedures. The existence of such ML systems pose certain challenges to the definition of these categories. Firstly, ML systems developed for healthcare often consist of multiple functions. Some systems could be composed of functions involved solely in creation or alteration of the care plan, while others contain functions that also ameliorate the efficacy or the efficiency of clinicians' involvement in care. Secondly, oversight prevention functions such as those utilised in Deep Safety can be simultaneously classified as diagnostic and operational. These formidable challenges indicate a need for a refinement of the definitions employed in the aforementioned classification.

To raise another point, when considering the application of AI technologies to accelerate the shift from acute to chronic care in Japan, one must understand that certain ideal policy ideas might not be plausible. As a pretense, the ideal way to provide timely and personalised care would be to promote self medication through the distribution of smart devices that not only collect and analyse data, but also suggest or even deliver treatments or contact professionals if intervention is required. To place this in more abstract terms, AI could assume tasks related to the interpretation of patient data, and reduce the operational intervention currently required by healthcare professionals including the necessity for referrals and charting. However, this would be very difficult to gain approval amongst

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[43] Masumoto, H. (2020).

healthcare professionals such as physicians, as it requires a complete overhaul of the legal architecture that anchors the healthcare system, in addition to the reconstitution of the current decision making and care delivery structure that is centred around physicians. This rigidity of the physician centred healthcare system and the legal architecture, is also one reason why certain strategies utilised by many other advanced regions and nations, namely the expansion of the scope of practice of healthcare professionals other than physicians, has met significant resistance in Japan.

2biii: Generation of new research questions

Why does the majority of nursing AI research focus on operational functions, despite larger impact being expected of diagnostic functions? The observations from the literature review and the two observations gives rise to a new research question that will also be investigated to supplement this paper. Expressly, if additional inquiries reveal general agreement to observation 1b that the diagnostic function of ML models can create a larger impact on healthcare systems compared to the effect of operational functions, it would suggest there would be a larger proportion of researchers developing these diagnostic functions. However, as revealed in section 2aiii, the majority of research projects linked nursing ML models can be classified as having operational functions rather than diagnostic functions. Furthermore, only one out of the five research projects from Japan could be classified as exploring diagnostic functions, with the other four mainly concerned with the amelioration of existing operations. Accordingly, it would be reasonable to inspect the reasons as to why the operational functions of ML models gather more attention in the field of AI research for nursing, and to question the means by which the perception of nursing roles affect AI research. Therefore, these two questions were formulated to examine the link between the rationale as to why diagnostic nursing ML research remains relatively overseen, and the general role of nurses in Japan.

Q1: Which major factors and stakeholders determine the role of nurses in Japan?
Q2: How does the perception of nursing roles shape the direction of Nursing AI research?

Part 3: Theoretical Sampling 1 - "Healthcare Policies and Legal Structures in Japan"

3a: Legal structures that respond to observations from the initial purposive sampling

This section will summarise the findings of the first systematic review, which will link policies and legal structures to the two observations (i.e. *Observation 1a: The creation of sustainable healthcare and the augmentation of care receivers' QoL are the two broad objectives of the implementation of ML. Observation 1b: Diagnostic functions have a potential for more transformative impact compared to operational functions.*) and the research questions (*Q1: Which major factors and stakeholders determine the role of nurses in Japan? Q2: How does the perception of nursing roles shape the direction of Nursing AI research?*) that were generated in response to the initial literature review. This section is divided into three sections, namey the elaboration of observations 1a and 1b, a deeper analysis of research questions, and the generation of a set of hypotheses that can be examined through a second systematic review and a narrative analysis of interviews.

In order to link the observations to policies, it is necessary to identify the current policies and legal structures that address the aforementioned concepts. In particular, this section will begin by identifying policies in Japan that are either under consideration or currently implemented that are aimed to achieve objectives mentioned in observation 1a. Furthermore, the latter part of this section will take a deeper look at the policies, legal structures, and stakeholders that together define the role of nurses, in pursuit of explanations that can respond to research question 2.

3ai(1): Current policies in Japan that address the sustainability of healthcare systems

Since 2013, the annual white paper published by the MHLW has raised the provision of sustainable health/long term care as a key policy issue of national interest. The latest version (as of 14 October, 2020) published in 2019[44] has been no exception to this trend. The fact that the cabinet office also lists

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[44] Ministry of Health, Labour and Welfare. (2019).

the provision of sustainable healthcare as a priority[45], demonstrates the significance of this issue in Japan. In particular, the year 2025 carries significant weight, as the entire cohort of baby boomers will surpass the age of 75. The government of Japan aims to establish and maintain a healthcare system that allows each resident to continue living in their accustomed regions, even when they require care. This section will provide an overview of current policies aimed towards the attainment of this objective, that will directly affect healthcare practitioners.

Raising the level of productivity through the implementation of ICT technologies

In order to accomplish the effective use of human resources, new policies were implemented to encourage the use of ICT technologies. For example, online consultations will be permitted in order to reach remote areas, and measures have been taken to establish an environment where physicians can utilise telecommunication devices to diagnose their patients. Additionally, certain conferences that were required to be undertaken in person due to safety and privacy concerns, can now be completed through online platforms as long as certain requirements are fulfilled[46]. Finally, nursing homes that have implemented smart monitoring systems with sensors that can efficiently supervise the elderly, will be preferentially compensated by the social security system. This is also to encourage the implementation of effective care infrastructure.

Securing the presence of physicians and nurses in regions and specialities in need

The lack of physicians in certain geographic areas and in certain clinical disciplines has been an ever present issue in Japan. Notably, there is a serious shortage of physicians in remote mountainous regions, as well as in pediatrics, obstetrics and gynecology. To address these issues in a more proactive manner, the national government established a regional health support centre in every prefecture. These centres collaborate with university health networks to help ensure a steady career plan for physicians practicing in these areas, and are allowed to install a special admission quota for medical school applicants who are willing to stay and practice in the region after graduation. The government also amended regulations for medical school curriculums, requiring medical school students to spend at least one month in regional care[47].

The national government has also implemented policies to ensure a steady supply of practicing nurses that can manage the rapid increase in the elderly population. In order to encourage nurses to return, they are asked to leave their contact information with the prefectural nursing organisation, so that they may be contacted during times of need. Furthermore, the national government has also implemented

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[45] Cabinet Office. (2018, p. 第2節 2).
[46] Ministry of Health, Labour and Welfare (2019, p. 368-369).
[47] Ministry of Health, Labour and Welfare (2019, p. 382-383).

policies that expand the role of prefectural nursing organisations. This was done so that nursing organisations can meet the specific needs of each prefecture, and take a proactive approach as improve services such as reinstatement support[48].

Additionally, the national government has taken a special interest in retaining and reinstating female physicians. According to the white paper released by the MHLW, the national government believes that it is important to cultivate an environment where female physicians can feel secure about undergoing various life stages, especially since the current ratio of females who pass the examination for medical licensure has approached one third, and female physicians compose a significant proportion of young physicians, especially compared to the previous generation. Notably, the government has implemented policies to increase child support within hospitals and has established offices that specifically cater towards female medical license holders who would like to return to the field. Some of the services provided by these offices include the introduction of medical institutions, planning for and carrying out training sessions for female physicians who have not practiced for several years, and administrative actions aimed at improving the working conditions of female physicians[49].

Workstyle reform for healthcare practitioners

Workstyle reform for healthcare practitioners is another urgent issue that is directly linked to the sustainability of healthcare systems. As mentioned previously in section 2aiii, which outlined key societal needs that ML is anticipated to resolve, the MHLW has highlighted physicians' overtime work as an area of key concern. In particular, the ministry has identified the major causes of overtime work. Firstly, there are the factors that exist in the clinical environment. These include the sheer number of outpatient visits that happen outside of designated consultation hours, surgeries that cannot be performed within the predetermined time span, the desire for each physician to provide the best possible care for patients, the amount of clerical work undertaken by practitioners, the concentration of responsibilities onto the physician role, and the lack of progress in terms of shifting tasks to other professions. Secondly, there are managerial issues that confront entire organisations and institutions such as the uneven distribution of physicians between various regions and clinical disciplines, the format of medical education, the lack of collaboration and delegation in providing regional community based care, and policies that induce certain behaviour amongst residents. Therefore, the ministry asserts that sustaining the quality and safety of healthcare is inseparable from the

[48] Ministry of Health, Labour and Welfare (2019, p. 383-384).
[49] Ministry of Health, Labour and Welfare (2019, p. 384).

maintenance of physicians' health, and that the current level of overtime work is acutely detrimental to the entire nation[50].

In order to achieve workstyle reform for physicians, the ministry has decided to engage this issue using three broad approaches. The first approach is to reform task management within medical institutions. That is to say, the ministry hopes to bring about a drastic change in physicians' and managers' awareness of this issue, encouraging medical organisations and institutions to realise how they themselves must extract traditional hierarchies and roles in order to adopt novel solutions. These novel solutions take the form of collaborating under a new consensus that involves all healthcare professionals, transferring operations, and applying ICT solutions that can raise the level of service efficiency.

The second approach is to functionally differentiate various medical institutions within the healthcare system. Notably, the ministry hopes to empower the regional medical care system, consolidate and prioritise medical institutions by function, and prevent overcrowding in acute care centres through the enrichment of services provided at primary care centres. Furthermore, the government hopes to enact policies that standardise the format of medical information so that it can be shared easily between various institutions, and correct the uneven distribution of physicians between various regions and clinical disciplines.

Finally, the third approach is to directly address residents in order to raise awareness of more efficient and effective ways to receive care[51]. The MHLW has taken a keen interest in task shifting and task sharing amongst physicians and other healthcare professionals, especially since similar concepts employed in other nations have not only increased efficiency but have also been successful in improving the quality of care and the level of accessibility to care. Additionally, the ministry plans to play a large role in the accomplishment of the second approach, as the coordination of regional care systems and primary care institutions cannot be undertaken without a standardised strategy that is shared amongst each individual physician and medical institution.

In order to further incorporate voices from the field, a series of interview and presentation sessions were held by the Ministry of Health, Labor and Welfare from June to July 2019, regarding the subject of task shifting, as it was being considered as part of the work style reform of doctors. Various healthcare professional groups presented their views concerning task shifting, followed by a

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[50] Watanabe, Y. (2019, p. 7).
[51] Watanabe, Y. (2019, p. 8).

discussion with panelists from the MHLW[52]. The presentations offered a variety of different perspectives and revealed deep fissures in the healthcare professionals' community, implying that consensus building not just amongst the stakeholder groups but within the stakeholder groups will prove to be a great challenge. These specific discrepancies and organisational structures revealed during the discussion will be discussed further in section 3b, which responds to research question number two. There was also a notable absence of stakeholder groups that directly represented the patients' perspective, with many stakeholder groups having largely diverging opinions regarding the achievement of "best practice for patients' wellbeing".

3ai(2): Current policies in Japan that are aimed at the augmentation of care receivers' QoL and address the shift from focusing on acute care to to chronic care

Summarised Chart

This chart provides an overview of the shift from acute to chronic care. Even though this chart only illustrates the transition and reduction of hospital beds, it provides the reader with a quantitative perspective regarding this general trend.
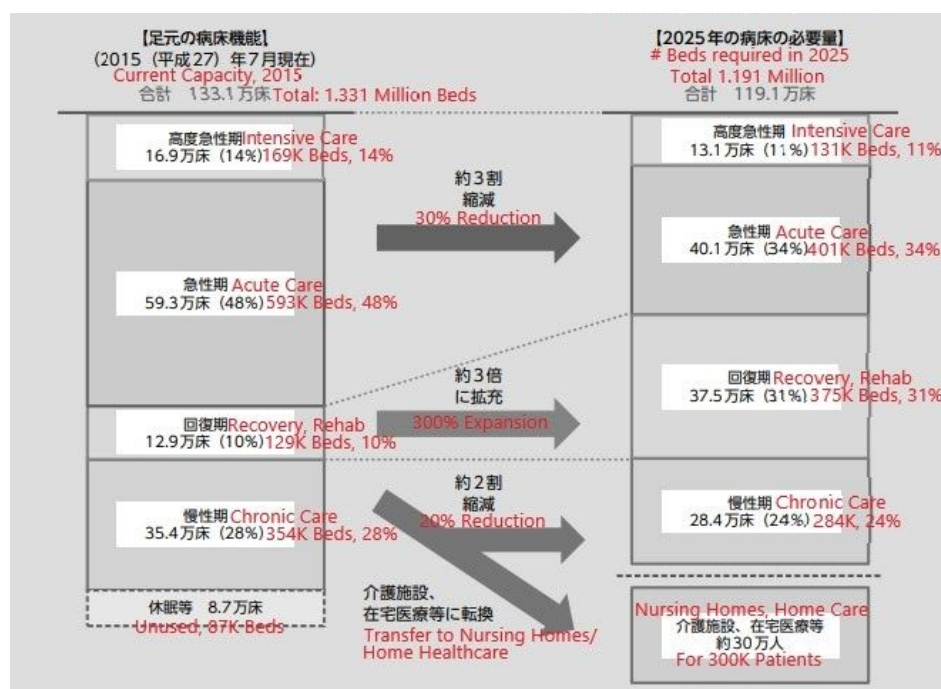
(From: Ministry of Health, Labour and Welfare, 2019 - Translation by author in red)[53]

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[52] Ministry of Health, Labour and Welfare (2019).
[53] Ministry of Health, Labour and Welfare (2019, p. 371).

The Introduction of Interprofessionalism (チーム医療)

There are many alterations occurring within the institution of Medicine as well as the policies that govern them. Generally speaking these alterations can be explained as a global shift from rewarding "quantity" to "quality", and from "acute treatment" to "chronic disease management". In particular, this global trend has been expressed through the enthusiastic implementation of "Interprofessionalism". While originally implemented in the United States and the United Kingdom during the 1960s, the concept has also found its way to Japan where the Ministry of Education, Culture, Sports and Technology and the MHLW, have placed since 2004 and 2011 respectively, the implementation of the "Healthcare team (チーム医療)" as a priority objective[54].

The endeavour towards the further integration of interprofessionalism and a shift from physician centred care to caring as a "Healthcare team", has continued to be an objective mentioned explicitly in the white paper[55]. In particular, the MHLW has established a platform for various stakeholders to discuss specific and concrete policy measures that should be implemented. Some of these specific policies have included the establishment of a new set of "specified acts (特定行為 Tokutei Koui)" that can be delegated to nurses who have gone through additional training, the abolishment of physician or dentist presence previously required for clinical radiologists injecting a contrast medium for CT scans or performing a chest X-ray, the abolishment of dentist presence previously required when a dental hygienist is performing preventative treatments, and permission for clinical laboratory technicians to perform nasal swabs for influenza tests. To this end, it is clear that discussions pertaining to the integration of interprofessionalism in Japan have largely remained within the division of labour, and have not explored the possibility of reconsidering the transformation of the roles of various clinical practices.

Strengthening Community Based Integrated Care systems (地域包括ケアシステム)

The MHLW aims to strengthen community based integrated care systems by encouraging residents to designate a general practitioner as a gateway to more advanced care, instead of over-utilising emergency out-patient visits. Unlike Canada or the United Kingdom where many residents register with a general practitioner or a family physician, residents in Japan can freely visit clinics and emergency outpatient rooms. While this might sound favourable, this lack of restriction not only reduces the amount of time physicians in acute care hospitals can spend with patients with severe cases, it also hinders continuity of care. Additionally, both physicians in private practice and in

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[54] Azuma, T., Kamiya, M., Okazaki, M., & Endo, K. (2013).
[55] Ministry of Health, Labour and Welfare (2019, p. 384).

hospitals do not have the incentive to raise their quality of service or thoroughly become acquainted with their patient, as they are incentivised by quantity rather than their quality of care. In order to address the situation, the ministry has decided to adjust health fees to better compensate medical institutions that possess primary care divisions[56].

Moreover, the government has enacted the law in 2017 for the enhancement of community based integrated care systems[57]. Under this law, the national government has decided to place financial incentives for regional administrations to manifest capabilities as a main contributor to insurer functions. In order to assess the progress of each regional administration in an equitable manner, this law outlines particular parameters that demonstrate the effective utilisation of data to identify, analyse, and resolve issues. Additionally, as the financial situation as well as staff organisation and know-how is unequally distributed between regional administrations, the Ministry of Health, Labour and Welfare and each prefectural government is mandated by law to aid regional administrations as they strive for the implementation of best practices.

The promotion of home medical care (在宅医療)

According to the white paper, the preparation of an effective home medical care regime is another urgent issue as many people in Japan, as a matter of fact, hope to receive care in their own house. Considering the rapidly ageing population, the completion of an effective and sustainable home medical care regime is as prioritised as the augmentation of clinical specialisation in acute care centres. Since 2013, home medical care has been listed with clear objectives under national health strategy. In 2014, each prefecture in Japan established a fund for community based integrated care systems, which certainly includes home medical care. Correspondingly, the prefectural government is expected to assume a larger role in the preparation and maintenance of home medical care regimes[58]. This also includes the assembly of a communication network that effectively educates the local community about new policies regarding home medical care.

Strengthening Visiting Nursing Stations (訪問看護ステーション)

In order to promote home medical care and create a sustainable network of healthcare professionals that can maintain Community based Integrated Care systems, the MHLW has focused on strengthening and maintaining Visiting Nursing Stations. To list a few of the most prominent tasks, nurses who work for Visiting Nursing Stations coordinate care, receive consultations from their clients, assist in rehabilitation, act as a liaison between the patient, family, municipal services, and the

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[56] Ministry of Health, Labour and Welfare (2019, p. 367).
[57] Ministry of Health, Labour and Welfare (2019, p. 213).
[58] Ministry of Health, Labour and Welfare (2019).

healthcare system, adjust the client's living environment, support the shift from in-patient care to home care, and participate in end of life care. In general, these nurses usually visit the client up to three times a week for up to 30 to 90 minutes per visit, unless clients are managing certain designated diseases that require more continuous care[59].

These Visiting Nursing Stations vary in size as well as organisational format. For example, some are linked to pre-established healthcare institutions, while others are privately run. Even amongst those that are managed privately, some consist of large franchises that span several regions, while other stations only cover a specific demographic within a region, and consist of less than 10 staff members[60]. According to a survey conducted by the National Association for Visiting Nurse Service, profitability and sustainability are very large concerns for Visiting Nursing Stations. In 2019, there was a total of 1376 new Visiting Nursing Stations while a total of 764 Visiting Nursing Stations either filed for bankruptcy or ceased operations within the same year[61]. This indicates that for every 10 new Visiting Nursing Stations, 5.6 nursing stations cannot maintain a level of ongoing sustainability. While Visiting Nursing Stations are expected to become a pivoting point for many avenues of care that support Community based Integrated Care Systems, the current situation poses formidable challenges.

3b: Determinants of Nurses' roles in Japan

The objective of section 3b is to respond to research question 2, which investigates the reasons as to why AI, namely ML technologies applied to nursing mainly consider operational functions over diagnostic functions, when diagnostic functions seemingly have a larger transformative effect. Since envisaged utilisations of AI are heavily dependent on the researchers' perception of the operator, which in this case are nurses, this section aims to comprehend how the nurses' role is determined in Japan. This objective will be accomplished through the delineation of policies, legal structures and organisations that take part in defining the role of nurses.

3bi: Legal structures that take part in defining the role of nurses in Japan

Firstly, as a regulated profession, the role and scope of practice are greatly influenced by the local institutional structure. In many countries, laws exist to broadly define Nurses' scope of practice as well as their role. While the nature of these legislations differ broadly across countries, as explained in detail later in this paper, it would be helpful to note that some key differences include the 1) level of

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[59] Ministry of Health, Labour and Welfare (2017).
[60] 三菱UFJリサーチ＆コンサルティング (2019, p. 6-9, Rep.).
[61] 一般社団法人全国訪問看護事業協会 (2020, p. 1-2).

independence by which a Nurse can operate, 2) the placement of a Nurse in the healthcare organisation, and 3) a variation in the protected Nursing titles.

In Japan, the basic role of non-medical professionals such as nurses have been defined in the fifth article of the *Act on Public Health Nurses, Midwives and Nurses* (保健師助産師看護師法, implemented in 1948) which reads as follows: "The term "Nurse" as used in this Act means a person under licensure from the Minister of Health, Labour and Welfare to provide medical treatment or assist in medical care for injured and ill persons or puerperal women, as a profession."[62]

The term *medical treatment* could be misleading, as it sounds equivalent to *medical practice*, the latter of which has been reserved for doctors as stated in the seventeenth act of the *Medical Practitioner's act* (医師法, also implemented in 1948) which reads: "No person except a medical practitioner shall engage in *medical practice*."[63] *Medical treatment* refers to actions that do not require pharmaceutical agents, prescriptions, orders, and other non-invasive procedures, while *medical practice* refers to advanced practices that include but are not limited to presenting a medical diagnosis, issuing prescriptions and certificates, and performing invasive procedures. Moreover, *assisting in medical care* as mentioned in the *Act on Public Health Nurses, Midwives and Nurses*, is defined as any task that should be performed by a physician but can be delegated to a nurse under his or her supervision. Hence one can say that under these two aforementioned articles, clinical tasks can be classified into three categories: "medical practice" which is only performed by physicians, "medical care that can be assisted"(this will be summarised as assistive acts for convenience) which should be performed by physicians but can be delegated to nurses under physician supervision, and "medical treatment" which is performed under nurses' discretion. Meanwhile, the specific boundaries of each of these categories are rather ambiguous and administrative interpretations of the law have transitioned over time. The following paragraphs will present a few examples of such transitions.

On one hand, a 1951 administrative interpretation of the *Act on Public Health Nurses, Midwives and Nurses* considers intravenous injections an act that lies beyond the nurses' scope of practice and

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[62] Article 5, Act on Public Health Nurses, Midwives and Nurses. Act No. 203 of July 30, 1948.
[63] Article 17, Medical Practitioners' Act. Act No. 201 of July 30, 1948.

should not be undertaken by anyone other than physicians or dentists[64]. Meanwhile, according to a judicial ruling, intravenous injections were considered to be an "assistive act". Thus, there was discord between the administrative interpretation and judicial ruling. Ultimately, a new administrative interpretation published 2002[65] overturned the previous decision, aligning its position with the judicial ruling.

On the other hand, there was a debate whether pelvic examinations performed under physician supervision would be considered "assisting in medical care". This surfaced as an issue in 2007 when nurses and physicians from Aichi and Kanagawa prefectures were brought to criminal trial for delegating pelvic exams to nurses. For cases from both prefectures, the judicial ruling was an indictment suspension. This indicates that unlike intravenous injections, there was no final judicial decision regarding the authorisation of pelvic examinations. The 30th article of the *Act on Public Health Nurses, Midwives and Nurses* reads: "No person other than a Midwife may practice the profession provided for in Article 3; provided, however, that this does not apply if said person practices such profession pursuant to the provisions of the Medical Practitioners Act (Act No. 201 of 1948)."[66] Thus, no one other than a midwife or a physician may perform tasks categorised under "midwifery". As shown in the 2007 case however, there has not been a clear legal distinction between acts categorised under "midwifery" and the acts that are not. In 2004, the administrative interpretation provided that a nurse must not perform pelvic examinations even under the command of a physician[67]. However, since an administrative interpretation of the law is not legally binding, this issue has not been comprehensively resolved.

Likewise, the differentiation between "assisting in medical care" and "medical treatment" is not necessarily straightforward. The observation of patient progress is usually classified under "medical treatment" as it does not have the potential to directly harm the patient. However, poor observations could also have significantly detrimental effects, as they play a crucial role in "assisting" diagnostic procedures. Hence, one could argue that clinical observations possess characteristics that can be classified into either of these two categories. Moreover, the judicial ruling regarding clinical observations have not been consistent, with some considering it a part of "medical treatment" and charging the nurse for responsibility[68], while other cases have considered it an "assistive act"[69], thus charging the physician for executive managerial liability.

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[64] Ministry of Health. (1951)
[65] Ministry of Health, Labour and Welfare. (2002).
[66] Article 30, Act on Public Health Nurses, Midwives and Nurses. Act No. 203 of July 30, 1948.
[67] Ministry of Health, Labour and Welfare. (2004.)
[68] 判例タイムズ1038号242頁(1999).
[69] 判例時報1790号119頁(2002).

These three examples illustrate the difficulty in marking the boundary between the acts considered "medical practice", "medical care that can be assisted", and "medical treatment". While the first two classifications involve invasive acts that could harm the patient, "medical care that can be assisted" can be relegated to nurses. At any rate, the differentiation between "medical practice" and "medical care that can be assisted" is far from being absolute, and remains rather dependent on the amelioration of nurses' analytical and technical expertise, historical backdrop, and the citizens' level of awareness. Accordingly, the nurses' scope of practice has the potential to dynamically adapt to the improvement of medical technology and nursing education. All things considered, these two legislations do not necessarily delineate the boundaries of the scope of practice, but rather serves a dual purpose of forming a hierarchical relationship in which the nurse is indisputably subservient to the doctor, while the doctor is practically forced to accept all responsibility for treatments under his or her supervision.

3bii: Health policies that take part in defining the role of nurses in Japan

Since the turn of the 21st century, the government as well as various clinician groups started to recognise factors that could threaten the sustainability of the healthcare system in Japan. One key strategy adopted by the government involved shifting certain tasks such as the removal of central venous catheters and the adjustment of insulin dosage, from physicians to other healthcare professionals. This was to serve the dual purpose of decreasing the workload of physicians as well as removing inefficiencies that are caused by the consolidation of decision making power onto the physician.

Discussions soon followed regarding the expansion of the nurses scope of practice. Many of the ideas were modelled after the *NP* position, employed in North America and Western Europe[70]. This *NP*, which will be elaborated later in detail, usually undergoes a masters' degree to receive additional training and gain technical, managerial and diagnostic expertise, often in a particular area of specialty. Though specific restrictions regarding the scope of practice vary by region and country, *NPs* are generally allowed to practice autonomously and in collaboration with other healthcare professionals. Some of the services they provide include ordering, performing and interpreting diagnostic tests, diagnosing and treating certain acute and chronic conditions, prescribing medications and other treatments, and counseling[71].

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[70] Ministry of Health, Labour and Welfare. (2010).
[71] American Association of NPs. (n.d.). What's a NP (NP)?

A series of discussions and public policy considerations held throughout the early 2010s, culminated in the establishment of a new exception of Nurses called "Tokutei Kangoshi" or RNs authorised to perform designated acts. The act introducing the Tokutei Kangoshi was put into force on the 1st of October, 2015[72].

As "Tokutei Kangoshi" was conceived as a result of compromise between various stakeholder groups including clinician organisations, academia, and the government, this new role is not considered a separate class or category of nurses, but rather an exception to the rule that allows RNs who have gone through a specific training regimen to assume certain medical practices that have previously been reserved for physicians without exception. The Tokutei Kangoshi role is fundamentally different from a NP role in that they are expected to execute certain tasks that require advanced skills and decision making capabilities, but are not allowed to practice autonomously, hence are unable to prescribe medication or initiate treatments. Tokutei Kangoshi are to execute these tasks as explained in the procedure manual when prompted by the physician. Designated tasks are divided into 21 categories, and RNs who desire to become Tokutei Kangoshi usually choose categories that are most pertinent to their specialty. Though this new policy has indeed provided an avenue for nurses to deepen their level of specialisation, it would not be accurate to say that the response has been overwhelmingly positive for both nurses and physicians.

Perhaps the total number of Tokutei Kangoshi could serve as an indicator of the level of acceptance it has gained amongst clinicians. Despite the MHLW aiming for 100,000 RNs who have completed a Tokutei Kangoshi training scheme, only a total of 2,646 have completed a course in at least one designated category as of July, 2020[73]. It is clear that it would be difficult to attain the goal that has been set by the government, and this relatively slow growth reflects the mixed response this policy has garnered from healthcare professionals.

The MHLW was quite enthusiastic about the expansion of the scope of nurses and the introduction of a new class of nurses similar to that of NPs. The Japanese Nursing Association also supported this development, seeing it as an opportunity to enhance the level of specialisation and rectitude of the nursing profession in Japan. However, not all nurses were keen on the opportunity to expand the role of nurses, citing the lack of compensation and a certain level of hesitation concerning the augmentation of legal responsibility[74]. The Japanese Medical Association also opposed the

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[72] Ministry of Health, Labour and Welfare. (2015).
[73] Ministry of Health, Labour and Welfare. (2020).
[74] M3.com編集部. (2016, December 10).

establishment of a new class of Nurses[75][76], stating that the purpose of NPs' existence remains undefined, and that medical care and decision making should be a task reserved for physicians in order to guarantee patient safety. Seeing that stakeholder groups were divided on their reactions not just between each other but also within their groups from the beginning, building rapport and reaching consensus proved to be exceptionally challenging. In many ways, policies leading to the establishment of the "Tokutei Kangoshi" were issued as a result of compromise. While nurses who have completed the courses to become Tokutei Kangoshi are allowed to execute more tasks than before, their level of decision making authority remains very limited. This lack of decision making authority is evidently becoming a choke point in the field of home hospitalisation and chronic illness management, hampering its diffusion and the transition from a focus on acute care to chronic care.

3biii: Stakeholder organisations that take part in defining the role of nurses

As described in the case of "Tokutei Kangoshi", certain stakeholder groups can exercise a large magnitude of influence on the role of nurses. These organisations are the MHLW, academia (both medical and nursing faculty), the Japan Medical Association, and the Japan Nursing Association. The following section will briefly describe the positions that have traditionally been maintained by these stakeholders.

The Ministry of Health Labour and Welfare

Firstly, the MHLW is not only a large stakeholder in the process of defining the role of nurses, it is the main provider of a common platform where other stakeholders can discuss their various viewpoints and the license distributor of healthcare professions. As a general statement, they desire to find innovative ways to raise the level of sustainability in healthcare, and to respond to demographic transitions. As a result, they have often embraced novel ideas such as task sharing and task shifting[77][78], while also developing a keen interest in the implementation of ICT solutions and approaches that utilise ML. They have attempted to fulfil this objective through the facilitation of communication and collaboration between various healthcare organisations as previously mentioned, and have presented solutions themselves. Additionally, as a part of the government, they monopolise authorities related to the legislation of new laws and policies that heavily influence clinical practice. However, unlike many of the other stakeholders, the Ministry does not represent a body of healthcare professionals and therefore does not have the same negotiating power as practitioner associations. In other words, the Ministry also cannot present laws and policies that displease professional organisations, as they could

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[75] Hashimoto, K. (2010, June 16).
[76] 日本医師会. (2011, November 18).
[77] Ministry of Health, Labour and Welfare. (2010).
[78] Sensho, Y. (2017).

technically go on strike and render healthcare in Japan completely inoperable. Therefore, while the Ministry can set the table of discussion, one could say that their leveraging power in the form of incentivisation and coercion, is rather limited.

Nursing Faculty

Academia has also played a key role in defining the role of nurses. In particular, key faculty members of nursing departments of universities or nursing schools have voiced opposition to the establishment of policies that expand the role of nurses stating that giving nurses pathologic diagnostic authority will shift their role from "caring" for the patient to "curing" the patient, which is a deprivation of the truest form of nursing. Moreover, they fear that the bestowal of these decision making authorities would simply create "mini-doctors" who have lost their clinical expertise as nurses. While their views are in contrast with the official position presented by the Japan Nursing Association, it does reflect the sentiment of a portion of experienced nurses. Irregardless, nursing and nursing education in Japan is conducted in general agreement that 'caring' in the field of nursing is a type of clinical expertise that is fundamentally different to medical expertise centered on 'curing', and is in essence a mother-like sense of protection[79]. However, unlike the concept of 'curing' the patient, which can be generally defined as removing or resolving a pathological situation, the concept of 'caring' is a lot more abstract and context dependent. Moreover, the two concepts of 'caring' and 'curing' have become incorporated into each other overtime, especially with the emergence of concepts such as Community Based Integrated care systems. The sentiments held by such nursing faculty reveal that various interpretations of the concepts such as 'caring' create disagreements within the nursing community.

The Japan Medical Association

As the most influential stakeholder group, the Japan Medical Association has consistently expressed hesitation expanding the scope of nursing. Notably, while the association recognises the current need for reconsideration of healthcare professionals' roles, they have explicitly opposed the establishment of the NP role as well as the "Tokutei Kangoshi" role when it was under consideration. The association has cited the following cases to justify their position.

Firstly, the association cites the differences between Japan and the countries that have already implemented an expansion of the role of nurses. For example, they cite that lower healthcare costs which can supposedly be achieved through the expansion of the role of nurses, is a larger issue in the United States where a significant portion of the population are uninsured. This is in stark contrast to

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[79] Nishida, E. (2016).

the situation in Japan where citizens and residents can receive subsidies under social insurance. Furthermore, they have stated that task shifting and role shifting from physicians to nurses is a more plausible solution in countries with more nurses per capita. In Japan, there is not only a chronic shortage of physicians but also of nurses. Secondly, the association also cites concerns regarding the quality of care[80]. In particular, they cite that the consulting and diagnostic services are protected by law, and that these services should continue to be completed by physicians in order to protect patient safety[81]. In other words, while patient care should be completed as a team, the healthcare system should maintain "medical control" or the delegation of work as assigned by the physician. Similarly, they have affirmed that ICT solutions and AI technologies should essentially be utilised to support the tasks undertaken by physicians, as they exercise medical control to orchestrate care[82]. The association insists that at the core, many of the issues related to sustainable healthcare can ultimately be solved only through the alleviation of the lack of manpower[83] and hopes that the government can implement measures to increase the number of physicians. To conclude, the Japan Medical Association, while acknowledging the need to discuss the transformation of the role of nurses, believe that changes should be made within the current framework, without largely amending legislation and organisational structure.

In spite of this, it would be an oversimplification to say that all physician organisations have uniformly opposed the transformation of medical legislature, policy, and organisational structures. It would be helpful to note that during a discussion session held by the MHLW regarding workstyle reform for physicians, the representative from the Japan Neurosurgical Society informed the group about the very positive response regarding Physician Assistants in the United States. Physician Assistants, like NPs are allowed to perform specific tasks that would be considered "Medical Practice" under current legislature. Therefore, one can observe that there are physicians, especially those who have worked overseas who recognise the potential of these new classes of healthcare professionals that bridge the gap between "Medical Practice" and "Assistive tasks".

Japan Nursing Association

Finally, as the stakeholder group representing Nurses in Japan, the Japan Nursing Association also has played a large role in defining the role of Nurses. If anything, they have well established ties with the Liberal Democratic party, which has been the dominant political party over the past half-century. However, it would be important to note that however large their contribution might be, they have not

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[80] 社団法人 日本医師会. (2009, June 3).
[81] 社団法人 日本医師会, Y. Kamayachi. (2018).
[82] Ministry of Health, Labour and Welfare. (2019).
[83] 社団法人 日本医師会. (2009, June 3).

been the primary source of influence regarding their role and their scope of practice. For example, in June and July 2019 when the MHLW invited stakeholder groups to express their position and discuss the topic of task shifting, only the Japan Nursing Association was invited from the field of nurses out of 30 professional groups. Meanwhile, the same meeting invited 13 physicians groups representing various clinical disciplines. This comes to show that relative to the absolute number of clinicians and the breadth of their discipline, their representative power is rather limited.

In terms of their official position regarding task shifting, the Japan Nursing Association affirms that there are on-site needs that cannot be met by the specific action training systems (i.e. Tokutei Koui, Tokutei Kangoshi) that does not go beyond the current legislation that limits nurses' practice to the "assistance for medical treatment under the direction of a doctor"[84]. Especially in areas where medical resources are limited, the association believes that there is a strong need for nurses to have new decision making authorities that are not permitted by current law and to take on more roles in order to support the medical recuperation and treatment of Japanese residents and citizens. On 4 July 2019, the president of the Japan Nursing Association personally presented a letter of request to the minister of Health, Labour and Welfare, asking for an opportunity for various stakeholders to gather and discuss the possibility of founding a clinical role with more diagnostic and decision making authority, similar to a NP[85]. Furthermore, the association has also been actively promoting the Tokutei Kangoshi system, hoping that further integration of nurses in advanced care roles can raise the level of awareness regarding nurses' positive capabilities. Nonetheless as previously mentioned, while the association officially supports an expansion of the role of nurses, dissenting opinions do occasionally surface from within the nursing profession, suggesting that support for change in the nursing profession is not necessarily unilateral. This lack of consensus building the nursing community, is another reason why they cannot exercise lobby power to the extent of physicians.

Patients: A general lack of representation

When it comes to healthcare policy, the patient's perspective could become overlooked as clinicians and policy makers tend to take center stage. The case of nursing roles is no exception to this trend, as the vast majority of discussions and research projects, while claiming to represent the best interest of patients, do not necessarily involve or actively investigate patients' perspectives on this matter.

Meanwhile, Shinkawa et al. conducted a qualitative study that involved an examination of patient's reflections on the involvement of Tokutei Kangoshi (specific acts nurses) in regional care. While this

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[84] 日本看護協会. (n.d.). 看護職の役割拡大の推進と人材育成.
[85] 日本看護協会, 広報部. (2019, July 8).

study is not a direct evaluation of Japanese patients' views on the diversification of nursing roles, it remains extremely valuable as it gathered genuine responses from patients who received care from Tokutei Kangoshi. In summary, the patients interviewed for this study responded positively to the involvement of Tokutei Kangoshi and the care they provided. Furthermore, communication skills (explaining pathologic and pharmacological concepts, listening patiently to the patient), the ability to bring about more holistic care through collaboration with other caregivers and a higher sense of affinity were identified as notable strengths[86].

While the findings from this particular study shed a positive light on patients' perspectives on the Tokutei Kangoshi role and consequently on the diversification of nursing roles, it is important to note the scarcity of current literature as well as the potential variation in the responses that could emerge, depending on the way the interview questions are framed. There remains a dire need for this kind of research, conducted from a neutral perspective that is not bound to a particular clinician group.

3c: Generation of Hypotheses 2

3ci: The *Act on Public health nurses, midwives and nurses* role in solidifying hierarchy

Firstly, the *Act on Public health nurses, midwives and nurses* leaves significant space for administrative interpretations, thus does not precisely delineate role divisions between physicians and nurses. However, it does firmly establish an unassailable hierarchy between these two professions.

To put this hypothesis into perspective, the Japanese government on one hand, has long desired to mobilise AI to relieve pressure from its healthcare system. On the other hand, the legal and organisational structures that anchor the healthcare system, have themselves become uncompromising barriers that preclude its implementation. In fact, while the laws that govern healthcare professionals' roles such as the *Medical Practitioners' Act* and the *Act on Public Health Nurses, Midwives and Nurses*, do not necessarily delineate or define the exact tasks and roles that should be delegated to each profession, they rather serve to create a steep irreversible power gradient that consolidates both decision making functions and decision making authority onto the physician role.

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[86] Shinkawa, Y. et al. (2014).

3cii: Operational choke points are caused by the concentration of decision making functions and authority

Secondly, the power gradient defined by its concentration of decision making functions and authority, is a structural impediment creating operational choke points and overwork for healthcare professionals. Furthermore, the rigid hierarchy characterising Japanese healthcare could be a key organisational factor that could hinder the maximal utilisation of ML technology, since communication and collaboration would be essential for its implementation. The effect of this structure could be well illustrated by the stagnation of interprofessional care or "Team-based care" in Japanese hospitals.

Indeed, the national government has attempted to implement interprofessionalism since 2004, since observing its contribution to quality patient care[87]. Under the concept of interprofessionalism, each healthcare professional collaborates with one another with mutual respect for each other's expertise, reconsidering traditional roles, while foremost placing the patient at the centre of care[88]. However, due to the power dynamic that exists within the healthcare sector, both doctors and nurses struggle to communicate and function as equal members of the team. While the aforementioned legal framework further serves to cement this relationship, the silo-like nature of the educational system for each system has also been specified as a potential contributing element to this phenomenon.

According to Azuma et. al., 40% of nurses surveyed attributed their "perceived lack of competence" as the reason why interprofessional work has not been practiced[89]. This was a peculiar discovery, considering how many nurses outside of Japan feel that they are working under capacity and feel competent in their role[90]. Additionally, 30.9% and 12.7% raised the "lack of cooperation and the dogmatism of doctors" and their "perceived role in the system as medical assistants tethered to the doctor" respectively, demonstrating the reality of the hierarchy that persists within the system. This could be one reason as to why the "Tokutei Kangoshi" system has not had a significant impact in reducing physicians' overwork, nor has it eliminated choke points that hinder the efficient provision of care.

Furthermore, there are not just legal, but also organisational and cultural barriers that prevent these potential benefits from being achieved, especially since non-medical professionals such as nurses are

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[87] Shinkawa, Y., Kai, K., Kouno, Y., Fukuda, H., Eduki, Y., Miyauchi, S., . . . Murashima, S. (2014).

[88] Azuma, T., Kamiya, M., Okazaki, M., & Endo, K. (2013).

[89] Azuma, T., Kamiya, M., Okazaki, M., & Endo, K. (2013).

[90] Chater, A. M., Williams, J., & Courtenay, M. (2019).

heavily restricted in their practice in countries like Japan. Legal barriers pertain to issues related to the role and the SoP within which nurses are expected to function. Organisational barriers refer to the structure of healthcare organisations. Particularly, while many other healthcare systems in advanced economies have adopted a team-based approach or an "interprofessional" approach in order to provide patient centred care, Japan maintains a rigidly hierarchical structure. Finally, cultural barriers refer to the balance of power within the healthcare organisation, and the issue of "task encroachment" or protectionist behaviour regarding occupational jurisdiction.

3ciii: Physicians, Nurses, Government in a standstill agreement

Thirdly, one can hypothesize that the various stakeholders shaping healthcare, intend to solve pressing issues while retaining the current structure. However, while the hierarchical system may have been effective in the past, it is uncertain whether it will be able to respond flexibly to the challenges reflected in modern society. It is to no doubt that the government as well as various stakeholders have recognised these pressing issues, introducing policies to make the healthcare system more sustainable, and striving to raise the Quality of Life achieved by care receivers. Nonetheless, these issues and objectives have been addressed through the attempt to limit physicians' workload and to shift a limited number of tasks to other professionals. In other words, the government as well as various stakeholders are trying to attain the aforementioned objectives, while fundamentally retaining the structure of the current healthcare regime.

The discussions that pertain to the introduction of NPs, which will be further elaborated in the latter sections of this paper, also serve to illustrate the traditional hierarchy that continues to be accepted in Japan. Though far from being the only defining qualities of a Nursing Practitioner, individual practice and especially the right to prescribe are two key components that characterise the role served by these professionals. However, discussions in Japan have progressed under the assumption that "Tokutei Kangoshi" or Specific-acts nurses will continue to work under the legal constraints of a RN, within a dependent relationship and without the authority to prescribe.

To further supplement this hypothesis, it would be helpful to briefly mention medical compensation mechanisms in Japan. These compensation mechanisms in Japan are largely based on piecework payment (出来高報酬), with the exception being the Diagnosis Procedure Combination payment method (DPC包括評価)[91] which is utilised in certain intensive care situations. Since practitioners are compensated per action in primary care, quantity is rewarded rather than quality. This leads to the toleration of a large deviation of skill level and expertise amongst practitioners, hindering the quality

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[91] Ministry of Health, Labour and Welfare. (2020).

of care. Moreover, this is also related to the unsustainable nature of Visiting Nursing Stations. Although visiting Nursing Stations are also compensated through piecework payment[92], many of their actions are not sufficiently compensated as they are not allowed to perform certain medical practices that add higher value. This could also be linked to the notion that labour should be hierarchically divided between institutions managed by physicians and non-physician professionals.

3civ: A Summary of the response to Research Question s

Taking into account the findings from the first theoretical sampling, this section will respond to the two research questions, which was generated during the initial purposive sampling. The thought in question is as follows:

Q1: Which major factors and stakeholders determine the role of nurses in Japan?
Q2: How does the perception of nursing roles shape the direction of Nursing AI research?

In response to question 1, the core factor determining the role of nurses in Japan would be the *Act of Public Health Nurses, Midwives and Nurses* and the *Medical Practitioners' act*, both enacted in 1948. These laws broadly classify healthcare tasks into three categories of Medical practice, Assisting in Medical care, and Medical Treatment, ordered from the most invasive to the least invasive. Additionally, there are various technological advancements and changing societal needs that shape the specific tasks required of nurses. Finally, prominent stakeholders such as the MHLW, the Japan Medical Association, the Japanese Nursing Association, and academic faculty also exert a very strong influence on the role of nurses.

In response to the second question, the perception of various healthcare roles definitely affects the direction of AI research as pertaining to the field of nursing. In particular, there are two factors that contribute to this phenomenon. Perhaps the most important factor is the hierarchical structure of healthcare in Japan which is firmly established within the aforementioned organisational structures and legal frameworks, which fundamentally considers physicians the "brain" and other professionals "hands and feet" of the organisation. Additionally, the underlying notion that as a baseline, societal issues and objectives will be met while retaining the current structures, further cements the direction of nursing AI research, that is geared towards operational functions.

In summary, an examination of the factors that define the role of nurses in Japan has revealed several key insights. First of all, the *Act on Public Health Nurses, Midwives and Nurses* leaves significant space for administrative interpretations on the scope of nursing practice. Therefore, it does not

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[92] Ministry of Health, Labour and Welfare. (2020).

precisely delineate the division of tasks between physicians and nurses. However, it does firmly establish an unassailable hierarchy between these two professions. Secondly, the "Tokutei Kangoshi" system has not had a significant impact in reducing physicians' overwork, nor has it eliminated choke points that hinder the efficient provision of care. Thirdly, various stakeholder groups such as nurses, physicians, and the government have not been able to agree on the specifics of new task allocations, nor have they been able to agree on clinical objectives that they are trying to achieve through task shifting. Furthermore, healthcare professionals in Japan have largely divided the role of healthcare into "caring" or "curing", assigning the former role to nurses and the latter to physicians. However, there has been significant disagreement even amongst nurses regarding the concept of "caring", with a palpable undercurrent affirming that nurses be deprived of their expertise, if they were to assume tasks and roles linked to "curing" the patient. Lastly, discussions pertaining to healthcare professionals' roles do not give patients and patient groups the opportunity to express their views, revealing a crucial lack of representation.

Conclusively, this paper considers that the lack of diagnostic ML tools for nurses and the comparative abundance of operational ML tools, may be derived from the notion that nurses are the "hands and feet" of the medical system while the physician is the "brain". While the hierarchical system may have proved to function effectively in the past, it is uncertain whether it will be able to respond flexibly to the challenges posed by modern society.

3d: Generation of new research questions

In light of these findings that were extracted from the first theoretical sampling process, 3 new research questions were formulated. These research questions will serve to guide the second theoretical sampling process.

Firstly, it would be necessary to investigate the specific choke points within the care process that are caused by the power gradient.

Secondly, it would be helpful to learn how countries other than Japan are responding to similar societal needs and choke points.

Finally, there must be a clear model as to how ML systems can be utilised to ameliorate the current situation.

Part 4: Theoretical Sampling 2 - "Identifying specific choke points where ML can be utilised"

4a: Identification of specific choke points in healthcare

This section will respond to the question regarding specific choke points caused by the power gradient. There are many choke points that hinder the provision of timely care in both hospital settings, as well as in home care settings. This section will mainly shed light upon the choke points that were observed in home-based care (also called "zaitaku-iryou" 在宅医療 in Japanese) due to three reasons. Firstly this is an area of healthcare where one can expect growth due to ageing demographic trends. Secondly, the government has expressed their intent to strengthen Community based Integrated Care systems, which will rely heavily on home care networks. Thirdly and perhaps most importantly, non-physician practitioners such as nurses are expected to assume a larger role in home healthcare, as professionals who can provide continuity of care while being situated in a position that is closest and most accessible to the patient, from both geographic and psychological standpoints. If anything, this mechanism could greatly improve the level of accomodation for chronic care management, if adapted for current needs and if certain choke points are unblocked.

Home care in Japan as an area of potential application

Since the advent of universal healthcare in Japan, it has become increasingly common for elderly patients to take their last breath in acute care. In fact, statistics from 1951 show that more than 80% of all deaths occured in one's own house, while more recent statistics from 2016 show that 75.8% of all deaths occur in medical institutions, demonstrating a complete reversal of trends[93]. However, in addition to the fact that this was not always the case, this tendency for the elderly to spend their last moments in the hospital, gives rise to disproportionately costly hospital bills during the last days of one's life. While this phenomenon called spaghetti syndrome[94], is not only limited to Japan but seen in various countries and regions around the world, the financial burden placed on the taxpayer is extraordinarily high in Japan where public insurance funds subsidise close to 90% of healthcare fees for citizens over 75 who have experienced a decrease in total income since retirement[95]. One could

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[93] Higuchi, N. (Ed.). (2018).
[94] Imhoff, M. (2004).
[95] Ministry of Health, Labour and Welfare. (2006).

argue that the subsidisation scheme could be structurally unsustainable, considering a national average life expectancy that surpasses 80 years and a vast array of medical treatments that are becoming increasingly complex.

To alleviate this overreliance and excessive use of intensive care in the terminal stages of illness, "Zaitaku-iryou" or home hospitalisations are being promoted as a more humane and family-centred alternative, as compared to the bureaucratic and institutionalised approach deemed necessary in intensive care. Even though there has been a reduction within the past 20 years, patients in Japan tend to experience a longer duration of stay in the hospital compared to many other developed countries and regions. To be precise, the average length of stay for all inpatient care was 28 days, as opposed to the OECD average of 7.7 days, and 7.4, 6.9 and 6.1 days in Canada, UK and the US respectively[96]. Therefore, a shift towards home hospitalisation and home chronic illness management can reduce the number of days spent in the hospital and consequently help curtail healthcare costs if implemented in an effective manner. Additionally, home healthcare would allow for the patient to recover in a more comfortable environment where one does not have to adapt to the schedule as determined by the ward, and encourage early independence as the patient can adapt to life after surgery or treatment and to new roles at home simultaneously. However, these positive effects are often mitigated by the choke points that are rooted in the consolidation of decision making authority. These specific examples will illustrate how these choke points emerge in real life situations.

4ai: Case Studies

These first two cases are excerpts from the Japan Nursing Association's presentation at a discussion session held by the MHLW[97]. The third case comes from a Nurse Practitioner with offices in both Illinois and Missouri, who provides a unique perspective as to how regulation policies have a direct effect on system efficiency and consequently, access to healthcare[98].

Case 1: Unable to offer proper non-invasive treatments, due to nurses' lack of authorisation to prescribe.

Patient background: Mrs. X is hospitalised in a medium sized general hospital in Japan, after suffering breathing problems due to pneumonia. She has been hospitalised for five days so far.

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[96] OECD. (2019, p. 197).
[97] Japan Nursing Association. (2019).
[98] Kleiner, M. M., Marier, A., Park, K. W., & Wing, C. (2016).

Situation: According to the nurse who assessed the situation, Mrs. X has not had any bowel movements for the past 3 days, she has a sacral pressure ulcer dressing that is peeling and needs new treatment, she requires vaseline or moisturiser for dry skin for the prevention of more pressure ulcers, and she is requesting a painkiller for chronic back pain.

Action: According to her observations, the nurse presented prescription suggestions to the attending physician, in order to care for Mrs. X.

Response: However, the physician is absent due to surgical work. Thus, the nurse and consequently, Mrs. X will need to wait until he can be contacted.

Analysis: Under current mechanisms, no medication can be used to treat Mrs. X until the physician returns to the ward and signs a prescription for the patient. As a result, there will be a deterioration of the pressure ulcer and a consequent augmented risk of infection, in addition to lingering back pain and discomfort.

Case 2: Unable to offer timely care at the care home in response to alterations in patient conditions. Need to bring the patient to the Emergency Room due to physician unavailability.

Underlying circumstances: Currently, there are many staff physicians who also act as attending physicians for patients at home or in care homes. A significant amount of time spent on hospital home visits, home visits, reports, contacts, receiving reports from visiting nurses, and consultations from facilities.
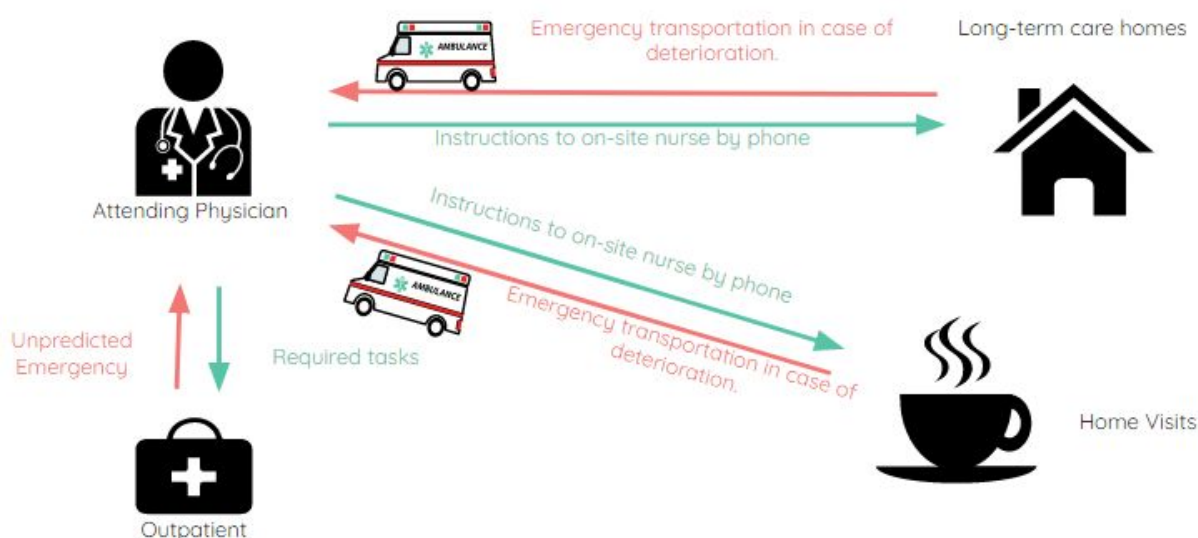
(Diagram Translated and Recompiled by Author[99])

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[99] Japan Nursing Association. (2019, p. 9).

Patient background: Living in a care home to manage several chronic conditions such as diabetes, hypertension, and paralysis on the left side due to a stroke The situation is mainly managed by the nurse, and the attending physician visits twice a month to adjust treatment.

Situation: Patient is showing very high levels of blood glucose and blood pressure is fluctuating. Shows risk of cardiac arrest.

Action: Need to obtain a new diagnosis from the attending physician to assess the situation and manage blood pressure as well as blood glucose levels.

Response: The attending physician is still in outpatient care. As a result, Mr. Y is taken to the Emergency Room.

Analysis: For patients being treated in care homes, the attending physician usually visits once every two to three weeks to assess the patient, then changes treatment depending on glucose/blood pressure levels in the case of Mr. Y. However, in the case where patients' conditions deteriorate and other assessments are needed, the physician must either be interrupted during other activities (e.g. outpatient) to attend to the patient. If not possible, the patient is often sent to the ER, increasing the strain on the attending nurse, the Emergency room, as well as the patient him of herself. Furthermore, even if the attending physician can be contacted, he or she must be interrupted during other tasks. Hence the consolidation of decision making authority not only causes delays in the delivery of care, but burdens both the patient as well as the attending physician. These choke points will be further analysed in the context of home medical care in the following section.

Case 3: Inefficiencies observed in out-patient primary care

Even though this case study is not from a source in Japan, it was included in order to illustrate how limitations in regulation policies can pose challenges to the efficient provision of care. Such clear examples of the direct effect of limitations in regulation policies are very difficult to find in Japan, considering the lack of diversification of decision making authority in the first place.

Situation: A NP with offices in both Illinois and Missouri describe the effect of regulation policies on efficient provision of care. According to this NP, the "Treatment for bronchitis can include cough syrup with codeine, and back pain may require pain medication. In Illinois, after examination and diagnosis, I can write these prescriptions. In Missouri, I need to delay the patient and interrupt the

physician to have him prescribe the medications. This creates unnecessary delays and may require extra trips for the patient."[100]

Analysis: An implementation of ML decision support systems in primary care without sufficient diversification of decision making authority, could cause similar issues that hamper timely access. If the legislation remains without amendment, the patient would have to make more stops until their treatment is initiated or altered, regardless of whether the non-physician practitioner has been empowered to make more comprehensive decisions with the assistance of decision support systems.

4aii Using ML to support decisions made by visiting nurses

Home care has recently gained a significant amount of support from clinicians, patients and governments, and is expected to assume a larger function within the healthcare system in Japan. This is due to the fact that the focus of medical care is shifting from acute to chronic care, as well as the need for the medical system to cultivate an environment that rewards quality of care over quantity. Meanwhile, operational and clinical choke points continue to plague home care systems, rendering its diffusion rather difficult. In order to delineate these choke points more completely, it would be beneficial to briefly outline some of the characteristics that set home hospitalisation and home chronic illness apart from conventional inpatient and outpatient care. While these choke points can be broadly classified as operational and clinical choke points as previously mentioned, these are often intertwined with each other. The following section will look at certain defining characteristics of home hospitalisation and home chronic illness management, in an effort to illustrate how each component can encompass more than one variation of choke points.

One comparable difference is in the formation of the medical interprofessional team caring for the patient. Unlike a hospital or a clinic where medical resources and personnel are centralised, resources and personnel are inevitably dispersed in home care. In Japan, healthcare professionals involved in home hospitalisation and home chronic care management almost always operate alone. On one hand, this encumbers smooth communication and hampers the maintenance of consistency across various caregivers, which poses a serious compromise to patient safety and could be defined as an operational obstacle that can create unnecessary clinical risk. Even though electronic communication using tablet devices and ICT software have become increasingly common, various professionals partaking in home care such as visiting nurses, physicians, and certified caregivers mainly communicate using facsimile or by phone for urgent cases. This is also due to the tendency for care professionals involved in home care to be older, relative to those working in more acute settings. On the other hand, as a

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[100] Kleiner, M. M., Marier, A., Park, K. W., & Wing, C. (2016).

result of the increased level of job independence, caregivers are required to have more decision making capacity than required in a clinic or a hospital setting. This is especially significant in the case of the aforementioned visiting nurses, or "Houmon Kangoshi (訪問看護師)". These nurses serving in home hospitalisation and chronic care management are hindered by the lack of resources that can support their decision making capability, especially when it is pertinent to deliver timely care.

While this will be further elaborated in the latter sections of this paper, it would be helpful to note that unlike many other countries that share similar issues, Japan has yet to adopt healthcare policies that expand the role of RNs or establish new classes such as NPs with augmented decision making capacity. This is also due to the aforementioned consolidation of decision making authority seen in Japanese medical institutions and legal architecture. A large part of this framework has been conserved not just for conventional acute care, but also when initiating care for home hospitalisation and chronic care management. Hence, all caregivers need to continuously refer back to the physician in charge in order to make changes to the prescription or to the care plan. Since every intervention must follow the order of: observation, analysis, and implementation, the physical and psychological distance between on-site staff such as the nurse or the authorised care worker and the physician can serve as a hindrance that causes significant delays.

Physicians are often encumbered under the current system as well. Since many physicians often divide their time between inpatient care, outpatient care, making rounds to care homes and visiting homes for routine checks, they need to stall other tasks in case of an emergency. This places a significant amount of strain on the physician, consequently increasing their workload[101]. Conversely, if on-site staff can access certain resources to confirm their observation and analysis, a consequent reduction in the time lag could make home hospitalisation and chronic illness management that much more attractive.

Secondly, the considerable involvement of the patient's family members is another distinct aspect of home hospitalisation and chronic care management. To emphasise the importance of this distinction, it could be appropriate to say that the unit of care involves the entire family in home hospitalisation and chronic care management, as opposed to caring for the individual in conventional care settings. As family members become the main caregivers of the patient while working in collaboration with healthcare professionals, the nurse must be well equipped to provide both clinical as well as emotional assistance. It is undeniable that the development and the eventual implementation of more accurate and affordable smart devices that can collect the patient's health data autonomously or with minimal

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[101] Ministry of Health, Labour and Welfare. (2019).

assistance, would greatly benefit both the clinician him or herself as well as the patient by reducing the amount of time lag between the stages of observation, analysis, and the implementation of countermeasures. Regardless, it would be unreasonable to assume that the introduction and diffusion of this technology would render healthcare professionals obsolete and inessential, since important aspects of healthcare are not limited to clinical and operational tasks but also to roles involving their position as authorised personnel that act as the legal foundation of certain confirmations and decisions, as well as their contribution of emotional support as previously mentioned in this paragraph [102].

With regard to the involvement of healthcare professionals in home hospitalisation and chronic care management, the most predominant actors are authorised care workers known as "Kaigoshi" and visiting RNs known as "Houmon Kangoshi". A typical visit of a visiting RN involves the assessment of health status (including physical assessment), supporting daily life and the emotional wellbeing of the client, medical treatments such as intravenous injections, wound treatment, catheter management, oxygen management, suctions, pharmaceutical management, and implementation of emergency care, receiving consultations from family members, implementing measures that prevent the deterioration of health, acting as a liaison with social or municipal services, rehabilitation, and supporting the transition from inpatient care to home care[103]. In addition to these tasks, the visiting nurse might also carry out specific treatments for clients with dementia, psychiatric needs, pediatric needs, or palliative care needs.

Since treatments are performed according to the orders made by the attending physician, the visiting nurse must also report key observations and intuitions. These observations are significant, since physicians rely heavily on these observations to make clinical decisions to which physicians and medical institutions are held responsible. Additionally, due to the fact that the physician can only make occasional visits, visiting nurses often need to present their own intuitions concerning the patient's care plan or prescription, taking into account their direct clinical observations and their perception of the patient and their family's emotional state, understanding of the procedures of care, and the patient's level of progress[104]. However, upon interviewing nurses with expertise in public health and nursing policy, the difficulty to express dissent in the face of a physician emerged as a common theme[105]. This not only diminishes the level of healthy collaboration between the visiting

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[102] Shishido, J., Ōya, T., & Kozuka, S. (2020).
[103] Japan Visiting Nursing Foundation. (n.d.). 訪問看護とは（医療・福祉関係者むけ）.
[104] Ministry of Health, Labour and Welfare. (2019).
[105] Mokko, T. (2020, September 17). [Online interview].

nurse and the physician, but ultimately serves to hinder the patient from receiving the best care, if it is not possible to have clear bidirectional communication between the home and the physician.

Interviewed nurses suggested that having AI systems that support or endorse their observations, conclusions, and suggested alterations to the care plan, would give them more confidence in their dialogue with the physician[106]. This is a key observation in discussing the impact of AI systems in the current medical structure, since it insinuates a potential for a transformation of power structures that could happen without radical change in legal structures, but rather through the empowerment of nurses' in discussion with the physician. In other words, the application of artificial systems can augment nurses' confidence in their own analysis, thus allowing for bi-directional communication and inclusive decision making while making use of the current physician-centred system. Additionally, the implementation of AI technology could also allow visiting nurses to spend less time on operational tasks, and engage in open dialogue with the patient and their family. The amount of time lag can be further diminished if visiting nurses with special qualifications can use the analysis and suggestions provided by AI decision support systems to directly alter care plans, write referrals or prescriptions under a certain formulary. However, these kinds of policies that involve the expansion of the scope of practice are very difficult to implement and garner support, in contrast to the level of acceptance observed overseas.

4b Comparative analysis of countries and regions outside of Japan

4bi NPs (NPs) and Advanced Practice Nurses

Since many developed and developing countries have seen nurses expand their role and their scope of practice, this section will focus on the approaches taken by other countries and regions with advanced economies, as many of their needs and issues reflect those in Japan. For example, 86% of the elderly population has at least one chronic problem with 33% juggling three or more in the United States. The number of primary care physicians who play a central role in the management of chronic illness, only increased 14% from 1980 to 2012 while the total number of physicians increased 73%, mirroring the specialisation of physicians in Japan[107].

However, in contrast to Japan, European and Anglo-Saxon nations have progressively turned to other healthcare professionals such as nurses to solve this issue, granting them the authority to lead complex care management teams, coordinate care, and execute tasks that were previously reserved for

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[106] Yoshie, S., Mokko, T., & Mizuki, M. (2020, August 7). [Online interview].

[107] Bauer, L., & Bodenheimer, T. (2017).

physicians. The establishment of a new class of Nurses called NPs (Nurse Practitioners) is a prominent example, as they work autonomously in collaboration with other healthcare workers. Meanwhile, the significant expansion of the scope of practice has not been limited to NPs, with RNs (RNs) and Advanced practice Nurses (APNs) in many leading countries being able to prescribe medication, lead outpatient clinics and manage hospitals. Underlying this expansion of the nurse's role are many signs that indicate an under-utilisation of Nurses' potential [108]. Even from this notion alone, it is possible to infer some of the differences between the situation in Japan and overseas. This section will compare the legal background and the organisational structure to that of Japan, and explicate upon the specific differences and its impact.

Legal and Historical background of development

The first difference between Japan and some European and Anglo-Saxon countries would be the way by which practice is regulated. In Japan, the titles of healthcare professionals are protected by national law, as with their role and SoP (scope of practice). In other nations such as Canada or the United Kingdom, while the title is protected by either the state, provincial or federal law, self-governing bodies have been given the right to fully or partially determine the role and SoP[109]. In other words, while practice in Japan is outlined strictly by law, the same cannot be said for some other countries where practice is defined by competence and self-regulation in addition to being anchored by law. This section will examine the notable differences in the legal background between Japan and other advanced countries with similar needs and objectives, and the way these differences in legislature translate into the SoP.

As of 2019, 13 European nations and regions (Cyprus, Denmark, Estonia, Finland, France, Ireland, Netherlands, Norway, Poland, Spain, Sweden, Switzerland (Canton Vaud), United Kingdom) and 5 Anglo-Saxon countries (Australia, Canada, New Zealand, United Kingdom, United States) have legislations that permit some form of nurse prescribing[110]. However, these countries and regions vary considerably in terms of the authority to prescribe, and the manner by which they are permitted to prescribe. One common factor would be the presence of a regulatory minimum educational requirement implemented to protect patient safety, though this can take various forms ranging from a compulsory component for RN certification or a continuing education programme, to a full fledged master's programme.

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[108] Crisp, N., Brownie, S., Refsum, C. (2018).
[109] Maier, C. B. (2019).
[110] Maier, C. B. (2019).

Many countries and regions have effectively established new advanced classes of non-physician healthcare professionals such as NPs, who have received at least a master's diploma, which focuses on equipping nurses with skills that are required for pathological diagnosis, prognosis evaluation, and prescription. For example, NPs in most US states are allowed to serve within the following advanced functions that are usually reserved for physicians: 1) ordering diagnostic tests, 2) performing or supervising lab tests, 3) Interpreting lab tests and diagnostic tests, 4) making diagnoses, 5) opening their own practice, 6) direct billing for compensation, 7) initiating treatment programmes, and 8) writing prescriptions[111]. In other countries and jurisdictions where RN prescribing is allowed while the NP position does not exist, prescribing tends to take place when there is a high degree of diagnostic certainty with a range of conditions that fall within the nurse's competence, unlike an NP in a primary care setting whose scope is broad and life span focused.

NPs were first created in the United States during the 1960s, out of a concern for underserved populations and their lack of access to primary care services[112]. In particular, the establishment of Medicare and Medicaid in the United States in 1965, accelerated the growth of demand for high-quality primary and acute care[113]. The term "NP" was coined for the first time at the University of Colorado, which had opened a demonstration project that was designed to educate nurses who can perform well child care in ambulatory care. During the 1970s, NP training programmes were developed at a graduate level, and this augmentation of educational standards was crucial in helping this new role gain acceptance within the general population[114]. During the early 1990s, new legislative decisions allowed NPs to file for direct compensation from public and private insurance schemes and prescribe medication. These measures have reinforced advanced nursing practice providers' ability to align their decision making processes with their physician counterparts[115]. More recently in the United States, the effectiveness of NPs have gained even further due to the COVID-19 pandemic. Until recently, NPs were only allowed to have full practice authority and assume all the functions listed above in 22 states. However, due to the explosion of demand in healthcare due to the pandemic, this has been expanded to 44 states[116]. Non-physician advanced practitioners such as NPs are expected to increase their functions and capabilities, as healthcare needs become more ubiquitous and diversified.

The NP role is considered a pioneering approach in role transitions for healthcare professionals. Meanwhile, it is important to note that it is not ubiquitous across other developed countries and

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[111] American Association of NPs. (n.d.). What's a NP (Nurse Practitioner)?
[112] Egenes, K. (2018, p. 24).
[113] Brennan, C. (2020, p. 83-84)
[114] Egenes, K. (2018, p. 25).
[115] Lenz, E. R., Mundinger, M. O., Kane, R. L., Hopkins, S. C., & Lin, S. X. (2004).
[116] Norful, A. (2020, September 11). [Telephone interview].

regions. Nevertheless, the propagation and acceptance of this concept has contributed to the establishment of advanced nursing roles and nurse specialist roles in various countries, including the specific acts nurse (特定看護師) in Japan. To summarise, the chart below compares the functions assumed by advanced nursing roles in 8 countries and regions that share similar healthcare issues and objectives as those observed in Japan. For the United States, two states were chosen to represent states that permit full practice and states that permit partial practice. These two states are Washington and Texas, respectively. Furthermore, countries and regions such as Germany, France and Hong Kong do not have official NP roles. Instead, the chart sampled other advanced nursing roles or specialist roles that similarly require additional education. From the chart, it is clear that advanced nursing roles in anglo-saxon countries such Canada, the United Kingdom and the United States encompass broad functions, permitting the interpretation of lab tests, diagnosis, as well as prescribing. While other France, Germany and Hong Kong do not ascribe functions that are as extensive as anglo-saxon countries and other unlisted European countries that have introduced NP roles, they have either partially or completely allowed performing or supervising lab tests, as well as opening their own practice. Moreover, while it was not possible to explicate this notion on the chart, these three countries and regions have introduced specialist clinical nursing roles that allow nurses to specialise and practice more autonomously within a certain field. As for Japan, an observation of the functions assumed by specific acts nurses revealed that their functions are extremely limited compared to their counterparts that fulfill advanced nursing roles in their respective countries. This comes to demonstrate that while the diversification of decision making authority is slowly but steadily under way in many other advanced countries that share many healthcare challenges, Japan has largely maintained the consolidation of decision making authority.

A Comparison of the Scope of Advanced Practice Nurses in developed countries & regions

	Ordering Diagnostic Tests	Performing/ Supervising lab tests	Interpreting lab tests and diagnostic	Making Diagnoses	Opening own practice	Direct Billing	Initiating Treatment Programmes	Prescribing
Canada (Ontario)	△ Partial	○ Permitted	○ Permitted	○ Permitted	○ Permitted	△ Partial	△ Partial	○ Permitted
France (infirmier spécialisé)	× Forbidden	? Unknown	△ Partial	× Forbidden	○ Permitted	○ Permitted	△ Partial	△ Partial
Germany (Altenpfelger)	? Unknown	△ Partial	? Unknown	× Forbidden	? Unknown	? Unknown	? Unknown	× Forbidden
United States (Washington)	○ Permitted	○ Permitted	○ Permitted	○ Permitted	○ Permitted	○ Permitted	△ Partial	○ Permitted
United States (Oklahoma)	○ Permitted	○ Permitted	○ Permitted	○ Permitted	○ Permitted	○ Permitted	△ Partial	△ Partial
United Kingdom (ACPs)	△ Partial	○ Permitted	○ Permitted	△ Partial	○ Permitted	? Unknown	△ Partial	○ Permitted
Hong Kong (Nurse Consultant)	× Forbidden	○ Permitted	? Unknown	× Forbidden	? Unknown	? Unknown	△ Partial	△ Partial
Japan	× Forbidden	△ Partial	△ Partial	× Forbidden	× Forbidden	× Forbidden	△ Partial	× Forbidden

(Chart compiled by the author[117118119120121122123124125])

4bii Diversification of decision making authority within the institutions of practice

In many of these countries, nurse prescribing has become increasingly crucial, with the progression of collaborative interprofessional work[126], which is expected to improve the quality of service and promote patient centred care. A few leading examples include the English National Health Service, which implemented a nation wide initiative that not only diversified the roles and scopes of practice first for nurses then pharmacists, but also redefined physicians' roles, as well as the Patient Protection and Affordable Care Act passed by the U.S. Congress that specifically addresses the policies that relate to the scope of practice[127].

Similar to Japan, medical institutions in many of these countries have traditionally been hierarchical with the senior physician or consultant orchestrating care at its peak, or exercising "medical control" to borrow the term from the Japan Medical Association. Though the vestige of this tradition remains to this day, numerous efforts by non-medical practitioners and policy makers slowly dismantled the silolike nature of professional education, and have nurtured the speciality of each profession. In many wards and healthcare teams, decisions are being made in a collective manner to a greater extent. Nurse prescribers working especially in primary care often collaborate with other primary care physicians, discussing care plans and taking responsibility for their own clinical decisions. This kind of environment will be very conducive to the eventual implementation of ML, considering that the protocol pertaining to the use of *Decision Support* systems must incorporate the views and strengths of each profession in healthcare, and since this technology is expected to further level the knowledge gap between different healthcare professions.

[117] Canadian Nurses Association. (2019).
[118] NP Association of Ontario. (2020).
[119] Shinoda, M. (2011).
[120] Matsumoto, N., & Kasagi, K. (2013).
[121] *Advanced registered NP-Activities allowed. 2000* (RCW) c 64 § 4; 1994 sp.s. c 9 § 425 (Wash.).
[122] *NURSING PRACTICE ACT, NURSING PEER REVIEW, & NURSE LICENSURE COMPACT TEXAS OCCUPATIONS CODE AND STATUTES REGULATING THE PRACTICE OF NURSING As Amended September 2013* (TOC) (Tex.).
[123] Evans, C., Pearce, R., Greaves, S., & Blake, H. (2020).
[124] Parker, J. M., & Hill, M. N. (2017).
[125] The Ministry of Health, Labour and Welfare. (2015).
[126] Lim, A. G., North, N., & Shaw, J. (2017).
[127] Ganz, F. D., Toren, O., & Fadlon, Y. (2016).

Revolutionising the workflow of medical institutions

The promotion of interprofessionalism and the expansion of the nurse's role and scope of practice are key elements that contribute to the maximal use of ML *Decision Support* technology. Nonetheless, these changes occurring in healthcare have already made significant contributions that have saved costs and improved patient outcomes.

Most prominently, the promotion of interprofessionalism and the establishment of roles such as the NP has revolutionised the workflow of entire healthcare organisations. On one hand, in most countries and regions with established medical institutions, diagnostic and decision making authority has been traditionally associated with and consolidated into the physician role, as is the current mechanism used in Japan. Under this mechanism, the healthcare professional in closest contact with the patient, who is usually the nurse, makes an assessment. Notably, the nurse is required to observe, assess, and grasp changes in the patient's general condition. If alterations in patient conditions are predicted, the nurse can immediately execute assistive tasks according to procedure manuals or instructions made by the attending physician ahead of time. However, if there are unforeseen changes in patient conditions, the nurse is required to contact the attending physician and wait for specific instructions before performing any task. Consequently, the delivery of care becomes delayed.
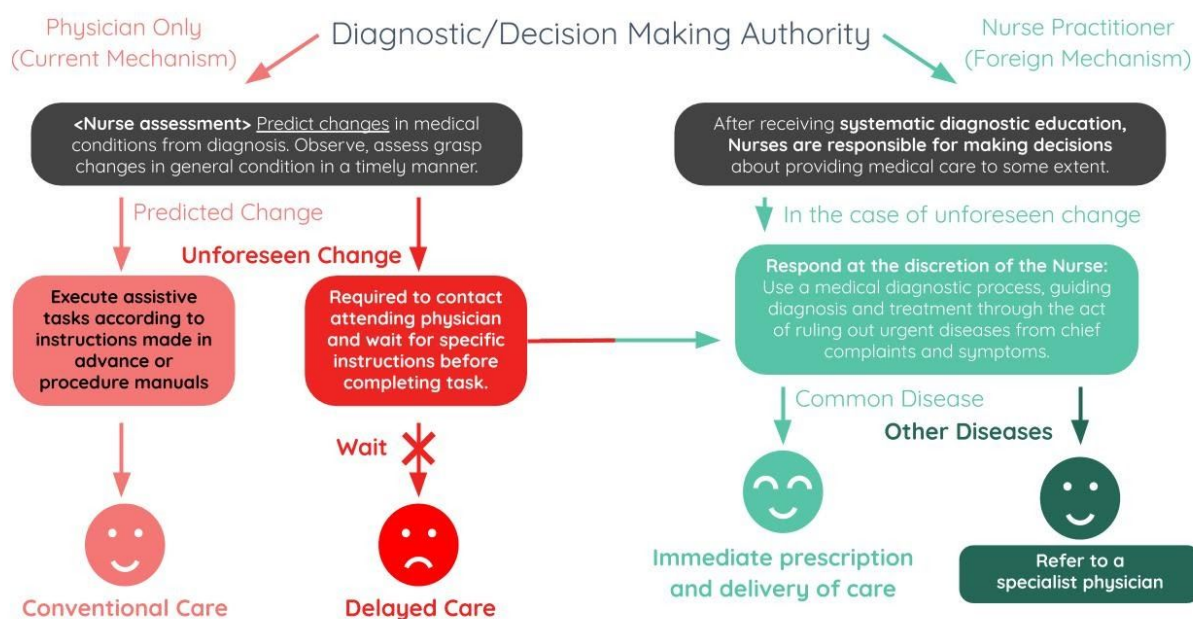

Diagram 2

(Chart translated and recompiled by Author[128])

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[128] Japan Nursing Association. (2019, p. 11).

On the other hand, the new mechanism employed under the NP and certain advanced practice roles has diversified the professions that yield diagnostic and decision making authority. In the case of NPs, they are responsible for making decisions about providing care to a certain extent. This is done after they have received systematic diagnostic education at the graduate level. Therefore, in case of unforeseen changes, practitioners can respond at their own discretion. Notably, NPs are expected to use a medical diagnostic process, guiding diagnoses and treatment through the act of ruling out urgent diseases from chief complaints and symptoms. In the case that the NP has concluded that the change in patient condition is due to common diseases, they can immediately proceed to delivering care and prescribing medication for the patient. If the practitioner concludes that the alteration is due to a complex condition, they can refer to a special physician. In summary, the diversification of decision making authority has the potential to expedite the delivery of care for a vast number of cases.

Positive economic impact in developed countries

Moreover, the literature in public policy has shown consistency over the notion that the expansion of the scope of practice and the proactive utilisation of nurses especially in the field of primary care, would be an effective cost saving measure. According to a literature search that examined the case of Massachusetts for the period of 2010-2020, the analysis estimated a cumulative statewide saving of $4.2 to 8.4 billion dollars[129], if primary care NPs or physician assistants' roles were liberated to function at their full capacity. An analysis that specifically focused on well-child visits showed that stricter nursing regulations would increase the price per visit by about 16$[130], which is a relatively large effect considering the typical price of a well-child visit resting at around $100. One analysis that examined visits to a U.S. retail clinic indicate that the average fourteen-day episode cost of a retail visit in a state with no independent practice (also known as full restriction) was $543, $484 in states with individual practice but no individual prescription, and $509 in states where NPs can both prescribe and practice independently, suggesting that strict restrictions on advanced Nursing practice does increase medical costs. The slight increase for the third cohort, could be due to the cost of direct acquisition of medication, which was not accounted for in the other two cohorts[131].

Additionally, Advanced NPs in the United States earned about $40.25 in 2013, approximately 60% the hourly wage for physicians in the same field[132]. Prescribing Nurses in the UK earn an average wage of approximately £40K, while GPs and consultants earn approximately £100K and even new residents earn over £40K in their second year[133]. Finally, considering that 3 to 12 NPs can be educated

[129] Reagan, P. B., & Salsberry, P. J. (2013).
[130] Kleiner, M., Marier, A., Park, K. W., & Wing, C. (2014).
[131] Xue, Y., Ye, Z., Brewer, C., & Spetz, J. (2016).
[132] Kleiner, M., Marier, A., Park, K. W., & Wing, C. (2014).
[133] Shirase, Y. (2011).

for the price of one physician and more quickly. advanced nurse training could be considered the fastest and least expensive way to address the primary care shortage[134].

In the meantime, cost saving benefits would be considered inutile if patient safety and treatment outcomes are compromised. Many sources of literature over the past four decades agree that patient outcomes of nurse-led treatments are comparable to those treated by physicians[135], as evidenced in clinical research that have examined the long-term health status of chronic disease patients, utilisation of specialists and emergency care resources, the frequency of hospitalisation[136], and management of non-communicable disease[137]. Additionally, several reports suggest that nurse-led treatments can augment patient outcomes, especially in managing blood pressure, blood glucose, the length of stay[138], and patient satisfaction[139][140][141][142][143].

Despite the lack of empirical evidence that links the abolition of collaborative agreements to the loss of quality of care[144] nurses' new roles and SoP has met continual resistance, and measures have been implemented to limit the speed of its expansion. For example in the United States, certain states require a dependent collaborative agreement between a NP and a physician in order to practice, prescribe medication or both[145]. Research findings suggest that these agreements diminish the number of NPs able to provide care, and other laws that limit specific specific elements of their practice such as the ability to prescribe certain categories of schedule drugs, order physical therapy or certify disability forms, could render NPs less effective since they need to continuously refer back to their supervising physician with whom they have a collaborative agreement.

Furthermore, in countries such as France[146]and the United Kingdom[147], nurse-led clinics and emergency response teams have served to fill gaps that were previously filled by employing younger

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[134] Fairman, J. A., Rowe, J. W., Hassmiller, S., & Shalala, D. E. (2011).
[135] Reagan, P. B., & Salsberry, P. J. (2013).
[136] Lenz, E. R., Mundinger, M. O., Kane, R. L., Hopkins, S. C., & Lin, S. X. (2004).
[137] Crisp, N., Brownie, S., Refsum, C. (2018).
[138] Stanik-Hutt, J., Newhouse, R. P., White, K. M., Johantgen, M., Bass, E. B., Zangaro, G., . . . Weiner, J. P. (2013).
[139] Stanik-Hutt, J., Newhouse, R. P., White, K. M., Johantgen, M., Bass, E. B., Zangaro, G., . . . Weiner, J. P. (2013).
[140] Horrocks, S., Anderson, E., & Salisbury, C. (2002).
[141] Lenz, E. R., Mundinger, M. O., Kane, R. L., Hopkins, S. C., & Lin, S. X. (2004).
[142] Maier, C. B. (2019).
[143] Crisp, N., Brownie, S., Refsum, C. (2018).
[144] Fairman, J. A., Rowe, J. W., Hassmiller, S., & Shalala, D. E. (2011).
[145] Barnes, H., Maier, C. B., Sarik, D. A., Germack, H. D., Aiken, L. H., & Mchugh, M. D. (2016).
[146] Shinoda, M. (2011).
[147] Shirase, Y. (2011).

residents and physicians overtime. In the emergency department, prescribing nurses not only triage patients, but also diagnose, treat, and prescribe for patients. This right to prescribe is exceptionally important, as nurses can initiate and conclude treatment all by themselves, and hence relieve the choke point caused by the shortage of physicians.

Debate regarding the diversification of decision making authority

In Japan and even in these European and Anglo-saxon countries, diversification of decision making authority is often met by opposition mainly from physicians; as nurses are largely in favour of increased specialisation and policy makers are interested in cost-cutting and improving access to care. It would be reasonable to say that some of these tensions emanate from the concern regarding the maintenance of a high level competency to guarantee patient safety. A representative example would be the case of a senior vice president for the Medical Society of the State of New York giving testimony to NY State lawmakers, that removing physicians' oversight of NPs "would seriously endanger the patients for whom they care"[148].

However other sources have revealed additional factors that contribute to this strain which include but are not limited to: increased market competition[149][150], and the traditional notion that nurses ought to be at the physician's beck and call[151][152]. For example, findings indicate that providing more independence for NPs in the United States increased nursing wages by about 5 percent and decreased MD's wages by about 3 percent[153]. Furthermore, some physicians in France vehemently opposed the formulation of a defined "nursing identity (rôle propre)" independent of physicians, as well as the establishment of a new class of "specialised clinical nurses (infirmiers spécialisés)"[154]. Many physicians in Japan continue to affirm that bestowing adequately educated and trained nurses with the right to prescribe would be "unnecessary for the benefit of the patient"[155].

The impact of new nursing roles on Patient Safety

Since the beginning of the NP movement and as the profession gained further recognition within society, many have been skeptical of the quality of care that can be provided by these new practitioners. Furthermore, the growing number of programmes within the past half century has raised

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[148] Pettypiece, S. (2013, March 8).
[149] Reagan, P. B., & Salsberry, P. J. (2013).
[150] Mizuki, M., Takahashi, M., & Kai, I. (2010).
[151] Shinoda, M. (2011).
[152] Tsujiwaki, K., & Matsushita, T. (2012).
[153] Kleiner, M., Marier, A., Park, K. W., & Wing, C. (2014).
[154] Shinoda, M. (2011).
[155] Tsujiwaki, K., & Matsushita, T. (2012).

questions regarding quality of care[156]. Therefore, it is extremely important that these questions and concerns are adequately addressed. One way to examine quality of care and patient safety, is to examine the level of malpractice between various professions. In particular, an examination of the number of malpractice payment reports can provide an index that can demonstrate the approximate level of safety achieved by each profession. This paper samples a study that used the National Practitioner Data Bank to obtain data regarding malpractice in the United States. Results revealed that over the 10 year span of 2005 to 2014, there ranged 11.2 to 19.0 malpractice payment reports per 1000 physicians, 1.4 to 2.4 per 1000 physician assistants, and 1.1 to 1.4 per 1000 NPs[157]. This shows that compared to physicians, NPs and Physician Assistants (another advanced care role that does not exist in Japan) are sued significantly less frequently. Nonetheless, it cannot be denied that MDs handle more cases with more complexity and risk, relative to those handled by NPs. Additionally, the same study also reveals that diagnostic skill remains a shortcoming for NPs. When compared to physicians, for whom 31.9% of malpractice reports were diagnosis related, NPs saw a larger ratio of diagnosis related malpractice allegations at 40.9%, indicating that diagnostic skill must be augmented in the case of NPs (51.2% for physician assistants)[158]. However, another malpractice report from 2019 showed that while 11% of family physicians have reported having been sued at one point of their career[159], as opposed to 1.1% of NPs[160]. Since family physicians and NPs handle cases of comparable complexity, it becomes possible to conclude that NPs are more likely to deliver safe care. Furthermore, many specialists agree that legal actions related to medical incidents are more likely to happen when communication and rapport is mitigated between the patient and the clinician[161]. Hence, one could also argue that this discrepancy between Family Physicians and NPs could not only be due to the delivery of safe care, but also to the level of trust building between the patient and the clinician.

4biii New nursing roles in home care, both as caregiver and instructor for the patient and their family

Amongst many developed countries and regions that share similar challenges, the diversification of decision making authority has not been the only response. In western Europe, a new system of home care called the "Buurtzorg model" has gained immense popularity. The underlying principle guiding the model, positions the nurse as a health coach not just for the individual but also for the family. The nurse will be emphasising and encouraging preventative health measures, providing necessary care

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[156] Brennan, C. (2020).
[157] Brock, D. M., Nicholson, J. G., & Hooker, R. S. (2016).
[158] Brock, D. M., Nicholson, J. G., & Hooker, R. S. (2016).
[159] Kane, L., & Shute, D. A. (2019).
[160] American Association of NPs. (2020, p. 1).
[161] Shishido, J., Ōya, T., & Kozuka, S. (2020, p. 120).

but also teaching and involving the individual and the family in the delivery of care as much as possible.

The Buurtzorg model, developed by a social non-profit enterprise in the Netherlands, focuses on the provision of social care in which professionals can work collaboratively in teams that were intentionally structured to be non-hierarchical. These teams provide not only clinical but also social and personal care to people who desire to receive care in their own homes. The teams, which cover a specific geographical area, are also self governed, which means that all the clinical and operational decisions are made by the team. Meanwhile, they can receive support from a coach and a central back office that facilitates constructive problem solving within the team[162]. The Buurtzorg model provides an approach that is in stark contrast to the standard procedures utilised to facilitate home healthcare in Japan, where healthcare and social care are provided disjointedly, with teams constructed in a hierarchical manner. In fact, patients utilising home healthcare often see many caregivers of various professions several times a day, and might sometimes not even see the same caregiver twice.

The Buurtzorg model is being tested in various locations, in partnership with local healthcare authorities such as the NHS Wales, non-profit organisations such as Soignons Humain in France. Additionally, studies in Aberdeen, Scotland[163] and London, England[164] have continued to investigate whether the Buurtzorg model can be effective outside of their initial context in a medium-sized Dutch city. Studies have shown that the Buurtzorg model adapted to other locations and contexts has been preferred by patients compared to previous experiences of home healthcare regarding continuity in care, increased proactivity from both staff and patient, and improved support of complex multiple chronic conditions[165]. Furthermore, participating nurses and family physicians have also found the system feasible and acceptable, as the ability to make clinical and operational decisions at the team level increased the level of efficiency, responsiveness, and creativity. However, some challenges included the establishment of a clear communication and team-management framework[166], the scrapping of pre-existing hierarchies and specialisms within the team, and the fact that the model requires management and bureaucracy to back off and allow the teams considerable latitude[167]. As most of the adaptive studies of the Buurtzorg model have been conducted in western European countries with limited expansion in the Far East, it would be interesting to see this model find a counterpart in Japan.

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[162] Drennan, V. M., Calestani, M., Ross, F., Saunders, M., & West, P. (2018).
[163] Leask, C., Bell, J., & Murray, F. (2020).
[164] Hamm, C., & Glyn-Jones, J. (2019).
[165] Drennan, V. M., Calestani, M., Ross, F., Saunders, M., & West, P. (2018).
[166] Leask, C., Bell, J., & Murray, F. (2020).
[167] Brindle, D. (2017, May 9).

Part 5: Discussion and Conclusion

5a: Discussion, Summary of major themes

This section will summarise the major themes that were extracted from the three sampling processes, namely the initial purposive sampling, first theoretical sampling, and the second theoretical sampling. Furthermore, these extracted themes will be utilised to formulate two practical findings, which in turn will be expanded into policy suggestions.

To begin, the major themes are as follows. Firstly, an analysis of legislative structures revealed that there is a power dynamic rooted in policy, between different healthcare professions. Moreover, policies and legislation in Japan do not necessarily delineate tasks between professions, but rather serve to consolidate decision making authority onto the physician role.

Secondly, this consolidation of decision making authority onto the physician role creates operational and clinical choke points that creates delays in the delivery of care and increases the burden on all parties involved in healthcare including physicians, nurses and patients. This choke point also adds to the challenges and societal needs that confront healthcare in Japan.

Thirdly, when it comes to the implementation of AI, notably ML systems in healthcare, the main objectives can be broadly defined as 1) raising the level of sustainability of healthcare systems and 2) improving the quality of life of care receivers.

Fourthly, the functions of ML systems in healthcare can be broadly classified as either operational or diagnostic. Diagnostic functions are expected to have a significant amount of impact, especially as systems or devices that can support the clinical decision making processes of healthcare professionals. However, diagnostic functions also require significant structural reform and nursing research pertaining to the application of ML systems are mostly related to operational functions. Furthermore, it is also clear that this classification is far from comprehensive, with a grey zone that exists between these two categories. Notably, "diagnostic" and "operational" functions are also context dependent, since some functions such as oversight prevention can be used to bring about the efficient and accurate execution of the care plan as well as its creation and alteration. Nevertheless, this

classification serves as a starting point for the analysis of policy constraints on the maximal adoption of ML technologies in healthcare. Furthermore, observations indicate that diagnostic functions that support or endorse conclusions and recommendations, would give nurses more confidence in dialogue with physicians. This would suggest that the implementation of diagnostic AI in nursing practice could have an impact in transforming rigid hierarchies, even though it remains difficult to instigate radical changes in legal structures that underpin healthcare roles in Japan.

Finally, an analysis of overseas solutions revealed that countries with similar societal needs have shifted to an interprofessional model that divides decision making tasks more equally between clinical roles. This is in response to the diversification of clinical needs, as well as the shift in focus from acute care geared towards infectious disease to the management of chronic care conditions.

5b: Discussion, extraction of key findings

Taking into account these five themes that were extracted from the sampling processes, two general findings were generated. These findings could serve as logical knowledge that can be applied to practice.

The first finding is pertaining to the global trend towards diversification of non-physician roles. Two factors, namely the complexification of healthcare needs and the implementation of more ML systems in healthcare, will be instrumental in driving this change. The basis of this finding is derived from the intuition that advances made in the diagnostic functions of ML decision support systems can make safe decision making capacity more readily available, while societal issues such as the complexification of healthcare needs will act as factors that accelerate the diversification of decision making authority, which has already been seen in other developed countries and regions.

The second finding is linked to the combination of innovative solutions. In particular, the themes extracted from the sampling processes seem to indicate that the benefits that are brought through diagnostic ML systems can be further enhanced through the diversification of non-physician clinicians who have decision making authorities. This intuition is derived from the first, second and fourth observation extracted from the sampling processes, which are namely the presence of a power dynamic rooted in policy, the emergence of choke points that are caused by the consolidation of decision making authority, and the impact of diagnostic function of ML systems. Diagnostic functions of ML systems not only have the ability to raise the standard of clinical decision making by acting as a fail-safe diagnostic checking mechanism as utilised in Estonia, but also the potential to make the act of diagnosing and prescribing something that can be undertaken with reasonable levels of safety by a

wider range of clinicians. However, current legislation as well as the hierarchy rooted in tradition, will not permit this. In other words, the impact of diagnostic ML functions could be mitigated if the current consolidation of decision making authority is maintained in Japan. In contrast, the impact can be maximised if a new framework can be developed to diversify those who yield this decision making authority.

5c: Policy suggestions

The two findings can contribute towards the formulation of three policy suggestions that will expedite the accomplishment of the two general objectives (1. augmenting the level of sustainability of healthcare, 2. improving the quality of life achieved by patients) linked to the application of ML in healthcare in Japan. To put it more precisely, these policy suggestions will address current choke points that include: the lack of workstyle reform, which undermines the productivity and wellbeing of healthcare professionals; the lack of clinicians in certain regions and specialties; operational choke points that are caused by the consolidation of decision making and the need to empower community based integrated care systems, as the focus shifts from single-factor acute care to chronic care, which requires the consideration of multiple causes and factors. These policy suggestions are as follows.

Policy suggestion 1) The first policy suggestion would be the diversification of decision making authority in Japan. As a general suggestion, the scope of practice of non-physician practitioners such as nurses trained in more advanced care, could expand to encompass clinical functions such as prescribing and diagnosing, as well as operational functions that would include designating public health nurses as managers of integrated regional care systems. One practical way to diversify decision making authority, could be to further employ pre-existing mechanisms such as prescription enquiries and expand its administrative interpretation to include other professions and functions. Another practical way would be make the best out of the ambiguity that surrounds the concept of assistive acts (診療の補助).

Policy suggestion 2) Secondly, the implementation of diagnostic ML systems can standardise the quality of practitioners' decision making, and ensure a level of safety across all clinicians. Furthermore, ML systems have the potential to give nurses an added sense of confidence to their decision making, in light of the existing power balance with physicians. In light of these benefits, it is imperative for legal mechanisms to be adjusted to allow diagnostic support provided by ML systems, albeit in a gradual manner.

Policy suggestion 3) In addition to diversifying decision making authority, there should be a way for these new clinicians with decision making authority and working in collaboration with ML systems, to file for direct billing from social insurance schemes for their service. This is because the consolidation of decision making authority is very related to the consolidation of compensatory authority, both of which are centred around the physician. In other words, without the right to directly receive compensation for their service, clinicians will not be able to work in a fully autonomous manner, and most of the operational choke points could remain unaltered.

The author hopes that the implementation of these three policy suggestions will expedite the achievement of the two general objectives of the implementation of ML in healthcare, through the removal of the aforementioned choke points. These policy suggestions will now be explained in further detail.

5ci: Suggestion 1) Diversification of decision making authority

Firstly, the diversification of decision making authority has the potential to bring significant improvements to the access of care, mainly through the two means of streamlining and supplementation. Granting non-physician clinicians more decision making authority would not only reduce the number of visits but also allow clients to initiate treatment in a timely manner from their own neighbourhood or even their own home. As briefly mentioned in previous sections, patients are often required to see a physician for repeat prescriptions or for slight alterations in their conditions that require amendments to their prescription or their treatment plan. This would be a tremendous advantage for patients with chronic conditions or for those living in non-urban regions, if visiting nurses or nurses stationed at nursing homes are able to initiate and conclude treatment while working with the assistance of *ML* decision support systems and in collaboration with other healthcare professionals. Additionally, the implementation of this amendment would help relieve the lack of physicians in regional primary care that has occured as a consequence to increased specialisation. Under this new proposed legislation, individual practice would allow primary care nurses to function as a "gateway to care" in non-urban areas, while allocating the more complex cases to physicians and thus reducing their burden.

Next, this policy recommendation could relieve the financial burden from the national health insurance system. As previously mentioned in section 4b, several sources have confirmed the cost advantage of nurse-led treatments, due to the lower labour costs as well as streamlining care and non-aggressive prescribing. Furthermore, several advanced practice nurses can be educated for the price of one physician. Hence, empowering then increasing the number of advanced care nurses

would be cost and time effective, considering that healthcare education is heavily subsidised by the government.

Moreover, the diversification of decision making authority into the field of nursing, should be implemented in tandem with the establishment of an accredited advanced care nursing programme. Since patient safety must always be a priority and the nurses' depth of knowledge remains a chief concern, both the advancement of nursing education and an appropriate level of precision must be attained by decision making systems at the same time. Concerning advanced nursing education, Japan could follow the example of master's degree programmes for NPs in Canada and the United States, or specialisation programmes that are required for RN prescribers in the UK and specialised nurses in France. Regarding the competence of decision support algorithms, stakeholders including but not limited to policy makers, AI specialists, healthcare professionals, and patient groups must agree on an acceptable level of accuracy, since algorithms like human practitioners will not achieve 100% accuracy.

Nonetheless, a complete overhaul of the legal structure concerning healthcare will not happen overnight. Consequently, it would be more realistic to make the best out of pre-existing systems and ambiguities regarding the nature of "assistive acts". To give an example of the former strategy, mechanisms such as pharmacists' prescription inquiry have already opened the door for non-physician clinicians to become involved in the decision making process. Therefore, expanding the administrative interpretation of prescription inquiries to include more professions and a larger variety of functions such as diagnosing and initiating treatment, could be a better solution situated at a practical level. As for the latter, the definition of "assistive acts" have constantly changed over time, and its boundaries have been dependent on skill as well as context. It might be more plausible to capitalise on this ambiguity and allow the diversification of decision making capability to become encompassed within a new administrative interpretation of "assistive acts". Moreover, Morita et al. have already been developing AI systems that detect and alert precarious movements made by young surgeons and trainees, in order to maintain a standard of safety while allowing them to gain more experience[168]. Perhaps a similar system can be developed for nurses, in which the system can delineate a more flexible boundary of "assistive acts" by taking into consideration the actions and skill level of the nurse.

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[168] Morita et al. (2020)

5cii: Suggestion 2) Consideration of legal mechanisms related to the implementation of ML diagnostic systems in healthcare.

There are two broad ways to permit the use of ML diagnostic systems in healthcare. The first is to rely completely on the clinicians' discretion and to maintain the current structure of the Medical Practitioner's act, while the second is to certify ML diagnostic systems as a medical device and allocate at least a portion of the liability onto the developer of these systems in case of malpractice.

Considering the first approach, under the current medical practitioners' act, physicians are basically allowed to use any device to assist their decision making, as long as they are also willing to bear full responsibility for any malpractice. This is similar to the approach utilised in Estonia, where physicians utilise ML systems to assist in their decision making processes. However, as mentioned in the previous policy suggestion, the administrative interpretation of laws such as the *Medical Practitioner's act* and the *Act on Public Health Nurses, Midwives and Nurses* should be altered to diversify the variety of professions that share decision making authority, in the case that this approach is employed.

Concerning the second approach, once diagnostic ML systems are registered as a medical device, it becomes significantly easier to diversify its clientele not just amongst various healthcare professionals but also to the general public. This would be a significant advantage that could expedite the diffusion of this technology. However, these systems would have to go through a rigorous testing process that would undoubtedly take years. Additionally, there are issues and questions regarding the levels of foreseeable risk that can be permitted for these systems, which are extremely difficult to build consensus across a wide range of stakeholders.

In response, this paper suggests that both of these approaches could be incorporated in a staggered manner. Initially, ML diagnostic systems would simply be considered a device used by physicians that assist their decision making. During this initial process, data should be collected in order to measure the level of precision that is being achieved by these systems. Following the confirmation of an acceptable level of precision, the administrative interpretation of laws should be expanded to diversify decision making authority to other healthcare professionals. It would be after following these steps and confirming the level of safety, that diagnostic ML systems become available to non-healthcare professionals, so that users can monitor their own health. Nonetheless, this is not to say that the first approach should be abolished altogether after the achievement of the popularisation of diagnostic ML systems through its approval as a medical device. Similar to the way certain pharmaceutical agents are

available over the counter while others are only available through prescription, pathological diagnosis, determination of disease prognosis and prescription should be maintained under authorisation of certified healthcare professionals, while monitoring healthcare status and diagnosing common diseases could be available to the general public.

5ciii: Policy suggestion 3) Direct billing for services provided by non-physician clinicians

The last policy suggestion is related to the first, in that the diversification of decision making authority should proceed hand in hand with the right to file for direct compensation for their services. The main objective of this diversification is to grant non-physician clinicians more autonomy and collaborate in a non-hierarchical manner with clinicians from other professions, in order to remove operational choke points that are rooted in the consolidation of decision making power. However, even if non-physician clinicians gain decision making authority, they would not be able to work with full autonomy if they can only be compensated through a contract with a hospital or a clinic, which bills under the physicians' name. Therefore, without the authority for direct billing and compensation, the positive effects of the diversification of decision making authority made possible through the implementation of diagnostic ML systems, would become undermined.

5d: Challenges to the implementation of Policy Suggestions

There are several significant challenges that make the suggestions made in the previous section very hard to implement in Japan. Many of these challenges are rooted in the organisational factor. For example, a very common theme seen across the literature pertaining to this topic would be the way by which each profession joins interdisciplinary discussions pertaining to the scope of practice with vastly different objectives. In fact, multiple sources identified the discrepancy between different professions' perception of each others' role, capacity and objective, as central to the reason behind the lack of cohesion during discussions in which representatives of different professions misread each others' contention. For instance, while nurses are interested in promoting patient centred care and in further specialisation of their profession, physicians often cite patient safety as the main rationale behind their opposition while also occasionally referring to the sustenance of traditional roles, while policymakers are interested in the economic and social benefits. Discussions held by the MHLW show that on one hand, a platform for discussion could allow various professions to arbitrate the disparities between the moot point held by each, while giving each party an opportunity to disembroil mutual misunderstandings. Meanwhile, without the clear establishment of a common goal, discussions have often become reduced to a stalemate, where various professions' sole interest becomes reduced

to the protection or the expansion of their territory, that is their role within healthcare. It would also be important to note that while the MHLW often serves as the initiator and facilitator of these interprofessional discussions, they are not completely neutral, nor are they immune to the bargaining power of other stakeholders. Therefore, one can surmise that the MHLW currently lacks the capacity to instigate radical changes to the organisational structure of healthcare in Japan.

Secondly, the lack of a unified consensus within stakeholder organisations, is another major reason why the diversification of decision making authority and notably the expansion of the nurses' role remains particularly difficult. For example, the Japan Nursing Association has officially recognised further specialisation of the nursing profession and the expansion of the nursing role as objectives they hope to achieve. However, many professors within the nursing community disagree, on grounds that further specialisation will lead to the loss of the core aspect of nursing, which should not be based on curing the patient but rather caring for the patient. On the other hand, various medical associations have been able to rally around a common goal, namely asking for a hike in medical remuneration and maintaining medical control, or centring the control of medical care around the physician. Since medical associations have been able to rally around these two objectives, results in significant lobbying power, especially with their expertise and traditional position within the hierarchy. Nonetheless, the Japan Nursing Association also carries significant lobbying power and maintains connections with the Liberal Democratic Party, which has been the most dominant political party in post-war Japan. It is therefore possible to deduce that the lack of a uniform consensus could definitely be a contributing factor regarding the mitigation of their influence, in the discussions surrounding the diversification of decision making authority.

While nurses empowered by the assistance offered by ML tools offer the potential to address increasingly pertinent healthcare needs, findings suggest that their contributions would be mitigated by structures and regulations that restrict practice, which is what is seen in Japan today. Compared to those in many other developed nations, nurses in Japan work under one of the most restricted conditions. Ever since the modernisation of healthcare in Japan, the relationship between physicians and nurses has remained generally unaltered, largely due to structures that implicitly yet firmly established subordination as a factor that characterises the nursing profession. In other words, nurses in Japan are linked to physicians by definition, and are consequently allowed nor expected to function with independence. Considering this power dynamic as well as other factors that contribute to its perpetuation (gender, levels of education, views held by interest groups), it would be reasonable to estimate that certain diversified practice policies implemented in other developed countries would be met with considerable resistance, and that its full implementation would not be realistic. Therefore,

this paper further recommends implementing measures in steps, restricting liberalised practice to areas of dire need. A first step could be to raise awareness of mechanisms such as prescription inquiries or to expand the interpretation of "assistive acts", as previously mentioned.

5e: Further Investigation

The three sampling processes followed by the analysis revealed numerous areas that would require further investigation. This section briefly outlines some of the major questions that emerged, but were not investigated in this particular study.

5ei: Bridging the gap between siloed systems

An analysis of literature, narratives, and interviews with healthcare professionals revealed that the healthcare system in Japan is particularly noticeable for its siloed organisations that are not only divided by profession (physicians, nurses, pharmacists, physiotherapists, etc.) but also by geographical region and clinical specialty. This is definitely one reason why the discussion platforms initiated by the MHLW have seen limited success in creating consensus that equally values the input made by each profession involved in patient care.

Possible causes include the lack of interprofessional training in Japan, as well as the traditional hierarchy and role division rooted in legislation but also in medical institutions. Looking forward, it is definitely important to slowly dismantle the silo-like organisational structure and increase horizontal communication, as patient needs become complex and patient conditions become increasingly multi-factored. Furthermore, it would be imperative to conceive methodologies that can create consensus and better collaboration between various professions. Nursing organisations could potentially contribute by considering the transition and transformation of their own role, in tandem with the roles of other non-physician roles.

5eii: Updating the curriculum to accommodate for ML systems

Another critical question regarding the diversification of decision making authority and the transformation of non-physician roles, would concern educating the next generation of professionals and updating current professionals. This is not simply about advanced care nursing, which would undoubtedly require additional training, but also about refurbishing nursing or medical education as a whole, in order to accommodate new needs and technologies. As one possibility, it would be interesting to see family physicians and advanced practice nurses trained together in the specific field

of the utilisation of ML. Nonetheless, devising a curriculum and choosing appropriate methods of supervision would require further research.

5eiii: Insurance and Remuneration Reform

Though this is not the most significant theme extracted from the study, reforming the remuneration scheme remains a question that is greatly intertwined with the quality of care, as studies of the system employed in the United Kingdom showed that well-designed billing schemes do incentivise better coordination of care. As mentioned on numerous occasions, there has been a clear shift from focusing on acute care, to chronic care and the coordination of various lifestyles within treatment programmes. Notwithstanding, the current billing system is largely based on acts that are directly linked to identifying causes of disease and implementing measures to cure or remove the cause. While this mechanism, also called piecework payment, is well adapted for infectious diseases, it is not the best fit for the majority of current health concerns that encompass multiple factors. Additionally, there has been a concern that the unbalance between market mechanisms on the consumption side, and the presence of public restrictions on the side of the provider, can easily cause moral hazards that decrease the level of efficiency, and increase the burden on social insurance[169]. In order to ameliorate the situation, it could be wise for the Japanese government to accelerate the shift towards bulk payment.

5eiv: Determining the appropriate level of decision making authority

The themes extracted from this study revealed that the diversification of decision making authority to non-physician practitioners in Japan has the potential to clear many clinical and operational choke points when used in tandem with diagnostic ML systems, considering that these systems have the potential to become a fail-safe mechanism that supports clinicians' decisions. Meanwhile, this research has yet to address the question of realistic boundaries that constitute the limit of what nurses can treat, diagnose and prescribe. This is not only important but also extremely challenging, since an extremely expansive scope of prescription and diagnosis would endanger the quality of care, while an overly restrictive scope would greatly diminish the effectiveness of new roles that are filled by non-physician professionals such as NPs, who have been trained to make pathological decisions. To put this into other words, if these new roles emerge as the main stewards of primary care and home hospitalisations, it would be necessary to define the boundary between the realm that encompass primary care and specialist or acute care. Contrarily, if this boundary is well established and

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[169] Shishido, J., Ōya, T., & Kozuka, S. (2020).

appropriately designed, the implementation of the aforementioned policy suggestion could be expedited.

In terms of this issue, perhaps an analogy could be drawn from the debate that used to surround the implementation of e-money in Japan. When e-money technology was first introduced in Japan in the 1990s, many legal experts discussed whether it is even legally possible for the Japanese government to permit money to exist electronically[170]. At that point, experts have concluded that it is indeed impossible to have "money" or "currency" in electronic form, under article 46 of the *Bank of Japan Act*. Even though this legal dilemma has remained unresolved, it is clear that e-money has become a part of daily life in Japan.

Why then, did e-money become widely used despite its legal standing remaining undefined? This dilemma was in fact, solved by setting a limit of 50,000 yen that can be stored in e-money devices such as transportation cards. In the 1990s, legal experts were considering the appropriate nomological response to cases such as the sudden disappearance of billions, if not trillions of yen. However, they were able to agree that a limit of 50,000 yen could effectively control the amount of risk, while appreciating the practicality and convenience of this new technology. Consequently, the experts were able to largely conserve the merits of e-money. In the case of realistic policy implementation in healthcare, it is equally necessary to discuss the appropriate level of risk as to conserve the merits of new ideas such as the diversification of decision making authority, instead of disregarding the idea all together.

5f: Final Remarks - "You can't make omelettes without breaking eggs."

This study investigated the impact of AI, especially ML technologies on the role of nursing. The central objective was to investigate AI's potential impact on the role of nurses and its related policies in Japan and identify structural impediments in Japanese healthcare that could hinder the realisation of such potential benefits. The analysis utilised a grounded theory method approach and was conducted in four phases which consisted of the Initial Purposive Sampling process, the first Theoretical Sampling process, the second Theoretical Sampling process, and the refinement of concepts. Subjects of analysis included ML functions, current and prospective societal needs in Japan, legislature related to the role of healthcare professionals, recent healthcare policies, stakeholders who partake in the definition of healthcare professionals' roles, and policies employed in other countries and regions.

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[170] Uchida, T., Kanda, H., Dogauchi, M., Morita, H., Fujita, T., Iwamura, M., . . . Sakamoto, T. (1997).

The themes extracted from the sampling processes were consolidated into the following five major observations. 1) The existence of a power dynamic rooted in policy. In other words, policies and legal structures in Japan do not exactly delineate tasks between professionals or define a set scope of practice. Rather, they serve to consolidate decision making authority onto the physician role. 2) Many choke points are caused by this consolidation of decision making power. These choke points complicate pre-existent societal needs and add to the burden of healthcare professionals and patients by hampering the timely administration of care. 3) As for ML technologies in healthcare, the general objectives of their implementation are to raise the level of sustainability of healthcare systems, and to improve the quality of care receivers, especially in chronic illness management. 4) Furthermore, the functions of ML systems in healthcare can be broadly defined as diagnostic or operational. On one hand, diagnostic functions are expected to make a larger impact on healthcare, and its application would require significant structural reform. On the other hand, nursing AI research is mostly related to operational functions. This is linked to the aforementioned power balance, legal structures, and traditional notions of hierarchy. 5) Finally, an analysis of overseas solutions revealed that countries with similar challenges have shifted to an interprofessional model that more equally divides decision making tasks between clinical roles.

Two findings were developed from these observations. Firstly, there exists an undeniable global trend towards the expansion of non-physician roles. Moreover, the implementation of AI in healthcare and the complexification of healthcare needs could lead to an even further expansion of non-physician practitioners' scope of practice, and the diversification of decision making authority. Secondly, innovative solutions such as ML functions and the diversification of decision making authority, can be combined to enhance each of their strengths. Correspondingly, this study proposes three policy amendments aimed to solve current choke points such as the lack of workstyle reform, lack of clinicians in certain geographical areas or areas of specialisation, delays in care due to the consolidation of decision making (or rather the inability for the vast majority of clinicians to operate autonomously), and the shift from acute to chronic care as well as the need to empower Community-based Integrated Care systems. The three policy proposals are 1) the reconsideration of diversifying decision making authority and the eventual delegation to other professionals, 2) permitting the implementation of diagnostic ML systems, which can standardise the quality of decision making and ensure a level of safety across all clinicians, and 3) delegating clinicians with new decision making authorities the right to directly bill social insurance systems for their service. Through the implementation of these policies, objectives such as raising the level of sustainability and

augmenting the quality of life of care receivers, could be achieved through the removal of operational choke points and the accomplishment of personalised care.

Meanwhile there are many factors and concepts that are yet to be addressed. In particular, issues regarding insurance reform (incentivising better coordination of care), bridging the gap between various professions (creating better ways to create consensus between siloed systems), altering the educational system to better account for ML systems (not just educating new clinicians but also to update current clinicians), further involvement of patients in discussions related to clinicians' roles, and setting realistic boundaries of primary care (what constitutes the limit of what non-physician clinicians such as nurses can diagnose and prescribe) remain crucial points for further investigation. The last area of further research is of particular importance, as the scope can neither be too broad or too narrow in order to achieve a level of effectiveness while ensuring a standard of care. In fact, this question has already been discussed in countries like the United Kingdom, where nurse prescribers work with a different formulary as the one used by physicians.

As a final remark, the author would like to mention that this study was initially launched as a short research paper, under the expectation that the project would develop as an investigation of micro-level influences of nursing AI systems on operational task flow. However, a deeper investigation of ML functions as well as current healthcare governance structures and the current societal needs confronting Japan, revealed that ML could truly revolutionise the overall structure of healthcare delivery and the power balance between various practitioners, if applied to the nursing profession. Compared to other developed countries that are confronted by similar societal needs and issues, the organisational structure of healthcare in Japan remains very rigid. Though necessary changes might not be achieved in a short period of time, themes extracted from the study offer reasons to hope that implementation of AI in nursing could come to be a disruptive breakthrough that can realise the sustainability of healthcare systems and improve patients' quality of life. Afterall, you cannot make an omelette without breaking eggs!

Appendix: "Key Nursing AI Research 2010-20"

Organised in order of publication year and surname:

1) F. Ladstätter et al., 2010 - "Application of artificial neural networks to a study of nursing burnout"[171].

   a) Research used neural networks to decipher non-linear cues of nursing burnout from documents.

2) Y. Son et al., 2010 - "Application of Support Vector Machine for Prediction of Medication Adherence in Heart Failure Patients"[172]

   a) The objective of this study was to apply a Support Vector Machine, a ML method used for data classification, to predict medication adherence in heart failure patients. Predictions made by these systems can be used to make evidence-based treatment plans.

3) J. Hunter et al., 2014 - "Automatic generation of natural language nursing shift summaries in neonatal intensive care: BT-Nurse"[173]

   a) The objective of this research was to determine whether a computer system can generate helpful natural language nursing shift summaries from patient records, in an autonomous manner.

4) G. D. Finlay et al., 2014 - Measuring the modified early warning score and the Rothman index: advantages of utilizing the electronic medical record in an early warning system.[174]

   a) The objective of this research was to reduce the number of false-alarm, seen in current early warning systems of impending cardiac or pulmonary arrest. Researchers used the Rothman Index, a patient acuity score that is based on the summations of excess risk functions that utilise data from electronic medical records.

5) F. Miyawaki et al., 2014 - "Development of scrub nurses robot system"[175].

   a) The development of an automated scrub nurse responsible for exchanging surgical instruments during endoscopic and laparoscopic surgery.

[171] Ladstätter, F., Garrosa, E., Badea, C., & Moreno, B. (2010).
[172] Son, Y., Kim, H., Kim, E., Choi, S., & Lee, S. (2010).
[173] Hunter, J., Freer, Y., Gatt, A., Reiter, E., Sripada, S., & Sykes, C. (2012).
[174] Finlay, G. D., Rothman, M. J., & Smith, R. A. (2013).
[175] Miyawaki, F., Yoshimitsu, K., Masamune, K., Fukui, Y., & Hashimoto, D. (2014).

6) P. Liao et al., 2015 - "Applying AI technology to support decision-making in nursing: A case study in Taiwan"[176]

    a) Research pertaining to the generation of nursing diagnoses using back-propagation neural networks.

7) A. Urashima et al., 2016 - "Development of Pointing and Calling Detection System for Nurses"[177]

    a) These researchers recognised that nurses in Japan employ a system of pointing at and calling out the names of various medications to prevent incidents. ML systems were able to detect occasions when nurses were pointing at and calling out medications. These ML systems can then be used to remind nurses about pointing at and calling out medications during clinical practice, in a less invasive manner.

8) S. Inoue et al., 2019 - "Integrating Activity Recognition and Nursing Care Records: The System, Deployment, and a Verification Study"[178]

    a) This paper introduced a system that integrates activity recognition and the collection of nursing care records. Activities are detected through sensors by ML systems and recorded with labels. Researchers hope to eventually develop a system that demonstrates near future prediction capabilities, that could predict the following day's activities from the previous day's records. This would be useful for proactive care management.

9) L. Minvielle and J. Audiffren, 2019 - "NurseNet: Monitoring Elderly Levels of Activity with a Piezoelectric Floor"[179]

    a) This research project introduced a system that combines a piezoelectric floor sensor with a convolutional neural network algorithm that can measure elderly physical activities. This tool can allow nurses to monitor patients' activities more accurately, without the need to manually enter data themselves.

10) N. Ohura et al., 2019 - "Convolutional neural networks for wound detection: the role of AI in wound care"[180]

    a) This research project evaluated whether or not convoluted neural networks can achieve high accuracy segmentations of diabetic foot ulcers and venous leg ulcers after being educated using data sets of sacral pressure ulcers.

[176] Liao, P., Hsu, P., Chu, W., & Chu, W. (2015).
[177] Urashima, A., Toriyama, T., Nakamura, M., Nakagawa, M., Oshima, J., & Nomura, T. (2016).
[178] Inoue, S., Lago, P., Hossain, T., Mairittha, T., & Mairittha, N. (2019).
[179] Minvielle, L., & Audiffren, J. (2019).
[180] Ohura, N., Mitsuno, R., Sakisaka, M., Terabe, Y., Morishige, Y., Uchiyama, A., . . . Takushima, A. (2019).

11) A. Barrera et al., 2020 - "Introducing AI in acute psychiatric inpatient care: qualitative study of its use to conduct nursing observations"[181]

    a) The objective of this research was to investigate whether AI systems can use digitally assisted nursing observations from sensors to reach similar conclusions as nurses individually investigating the status of patients

12) J. Song et al., 2020 - "Predictive Models for Surgical Site Infection (SSI) in Patients with a Permanent Pacemaker (PPM) Using ML Methods"[182]

    a) This research project compared the prediction abilities such as specificity, accuracy, sensitivity, and positive predictive value of three different predictive ML models. These models were logistic regression, decision tree, and support vector machine. All three models showed excellent specificity and accuracy in predicting surgical site infection, showing rates of over 98% and 96% respectively.

13) S. Tsuru et al., 2020 - "Nursing record innovations aimed at harmonizing structured clinical knowledge among doctors and nurses"[183]

    a) This research project created 778 Patient Condition Adaptive Path Systems that summarise information in clinical progress sheets by linking new input with cases previously described in electronic medical records. This PCAPS system can be applied to raise the quality of descriptive records, while reducing the time required to complete them.

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[181] Barrera, A., Gee, C., Wood, A., Gibson, O., Bayley, D., & Geddes, J. (2020).

[182] Song, J., Buenaventura, E. S., Cohen, B., Liu, J., Yao, D., & Larson, E. (2020).

[183] Tsuru, S., Tamamoto, T., Furuya, H., Nakao, A., Fukuyama, M., Tanizaki, K., & Yahagi, N. (2020).

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