Documents for the Record – 11/29/2023 HE Hearing

Majority:

- November 29, 2023 article from npj Digital Medicine (submitted by Rep. Miller-Meeks)
- November 29, 2023 statement from American College of Surgeons (submitted by Rep. Joyce)
- November 29, 2023 statement from Johnson & Johnson (submitted by Rep. Miller-Meeks)
- November 29, 2023 letter from Premier Inc.
- November 29, 2023 letter from TechNet
- November 27, 2023 letter from Consumer Technology Association

Minority:

- November 29, 2023 statement from American College of Surgeons
- November 29, 2023 letter from National Nurses United
- November 29, 2023 letter from Premier Inc.
- November 27, 2023 letter from Consumer Technology Association
- November 1, 2023 statement from Bonnie Castillo, Executive Director, National Nurses United

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PERSPECTIVE OPEN

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Effectiveness of artificial intelligence screening in preventing vision loss from diabetes: a policy model

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The effectiveness of using artificial intelligence (AI) systems to perform diabetic retinal exams ('screening') on preventing vision loss is not known. We designed the Care Process for Preventing Vision Loss from Diabetes (CAREVL), as a Markov model to compare the effectiveness of point-of-care autonomous AI-based screening with in-office clinical exam by an eye care provider (ECP), on preventing vision loss among patients with diabetes. The estimated incidence of vision loss at 5 years was 1535 per 100,000 in the AI-screened group compared to 1625 per 100,000 in the ECP group, leading to a modelled risk difference of 90 per 100,000. The base-case CAREVL model estimated that an autonomous AI-based screening strategy would result in 27,000 fewer Americans with vision loss at 5 years compared with ECP. Vision loss at 5 years remained lower in the AI-screened group compared to the ECP group, in a wide range of parameters including optimistic estimates biased toward ECP. Real-world modifiable factors associated with processes of care could further increase its effectiveness. Of these factors, increased adherence with treatment was estimated to have the greatest impact.

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INTRODUCTION

Digital Technology, including autonomous Artificial Intelligence (AI), has the potential to improve patient outcomes, reduce health disparities, improve access to care, and lower health-care costs[1–5]. Typical metrics for evaluation of new technology focus on efficacy[6,7]. In the case of diagnostic AI systems these efficacy metrics translate into diagnostic-accuracy measures, such as sensitivity and specificity, compared to an agreed upon reference standard[8]. Multiple AI systems have been shown to be safe and efficacious using such metrics, resulting in FDA De Novo clearance and clinical use[9–11]. While these diagnostic-accuracy metrics correctly estimate the efficacy of the diagnostic AI system, they do not give information on the overall impact (effectiveness) of the AI system on patient outcomes[6].

Instead, the impact of implementing AI on patient outcome is dependent on many factors beyond the diagnostic accuracy of AI[7]. These factors include characteristics of the disease, such as prevalence, and natural history, as well as potential frictions in the care process, including access to care, adherence with a recommended referral, and adherence with treatment and management recommendations. In addition, treatment itself where indicated is unlikely to be perfect, and may itself lead to imperfect outcomes. Therefore, even if a diagnostic AI with perfect accuracy is implemented, outcomes will be affected by these frictions associated with processes of care, as will potential efficiency gains, and differential effects on health inequities. These processes of care frictions/imperfections may be less obvious, as they cannot be determined from inspection of the standalone AI system, but instead depend greatly on how the AI system is integrated into the care process as well as the health delivery network. While some AI systems, such as those used in the critical care environment may affect patient outcome in real time, in many cases, AI systems are designed for chronic conditions, where a difference in outcome may take years or even decades to manifest. Thus, process-of-care metrics need to be considered in addition to outcomes to determine whether it is worth designing, developing, validating, implementing, regulating and reimbursing such AI systems[6].

An example of an AI system that has the potential to affect real-world outcomes is the first diagnostic autonomous AI (IDx-DR, Digital Diagnostics Inc, Coralville, Iowa). It received US FDA De Novo clearance in 2018 to autonomously, that is without human oversight, diagnose diabetic retinopathy and macular edema—Diabetic Retinal Disease (DRD)[12]. Clearance was based on efficacy, as determined in a preregistered clinical trial[11], which provided information on the diagnostic-accuracy metrics of sensitivity and specificity, but not on effectiveness or impact on patient outcomes. As diabetes is a chronic disease, it will take years to determine this impact, requiring following each patient that interacted with the AI system to a disease endpoint for years. Given the lack of such empirical data of the impact on patient outcome (vision loss), we modeled screening strategies and the downstream care process, as the Care Process for Preventing Vision Loss from Diabetes (CAREVL) policy model, to estimate the impact on patient outcome (vision loss).

The primary purpose of this study was to develop the CAREVL model and leverage it to determine the differential impact of autonomous AI-based diabetic retinal exams ('screening') vs screening performed in the clinic by an eye care provider (ECP). Secondarily, its purpose was to explore how processes of care modulate the effectiveness of screening strategies.

RESULTS

All analytical inputs are listed in Table 1 and detailed in the Supplementary.

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Table 1. Parameters for the decision model.

Parameter Description	Base-case estimate	For sensitivity analysis	
		Low	High
Population-metrics: Prevalence and natural history of disease			
Prevalence of Metabolic DRD[11]	0.22	0	0.40
Prevalence of Ophthalmic DRD[11]	0.0088[a]	0	0.10
Prevalence of DRD with Vision Loss[42,43]	0.01	0	0.05
No DRD to metabolic DRD[44]	0.05	0	0.15
Metabolic DRD to ophthalmic DRD[44]	0.02	0	0.20
Ophthalmic DRD to vision loss[39,40]	0.075	0	0.20
Vision loss to irreversible vision loss[45]	0.37	0	0.50
Diagnostic-accuracy metrics: Sensitivity and Specificity of Screening Strategies			
Sensitivity of screening for DRD with AI[11,13,17]	0.87	0	1
Sensitivity of screening for DRD with ECP[46]	0.33	0	1
Specificity of screening for DRD with AI[11,13,17]	0.91	0	1
Specificity of screening for DRD with ECP[46]	0.99	0	1
Process-of-care metrics: Screening and Referral for Appropriate Care			
Probability that patient follows up for eye care after AI screen positive[4,47–49]	0.75	0	0.95
Probability that patient follows up for eye exams after ECP screen positive[47]	0.29	0	1
Probability of patient Accepting Screening by AI[50]	0.95	0	1
Probability of patient Accepting Screening by ECP[4,5,27,47,51,52]	0.20	0	0.80
Probability that patient with Vision Loss Accepts referral to ECP[28]	0.58	0	0.75
Process-of-care metrics: Effectiveness of treatments for DRD(Progression of treated disease)			
Metabolic DRD to ophthalmic DRD[44]	0.01	0	0.05
Ophthalmic DRD to vision loss[39,41,53]	0.02	0	0.50
Vision loss to irreversible vision loss[54]	0.034	0	0.05
Process-of-care metrics: Probability of Adherence to Treatment			
Adhering to metabolic management[24,25,55]	0.24	0	1
Adhering to ophthalmic management[26,28]	0.26[a]	0	1
Adhering to DRD vision loss management[28]	0.41[a]	0	1

[a]Calculated values: see Supplementary.

Base-case and sensitivity analysis

For the base case, in the no-screening strategy the proportion of adults with DM who are estimated to develop any vision loss at 5 years is 1637/100,000; it is 1625/100,000 for the ECP screening strategy, and 1535/100,000 for the AI screening strategy. Thus, the proportion of DM participants who develop vision loss in the model with AI-based screening (1535/100,000) is estimated to be 102/100,000 lower compared with no-screening (1535/100,000) and 90/100,000 lower compared with ECP-based screening (1625/100,000). The difference between no-screening and ECP is 12/100,000. Thus, CAREVL suggests that introduction of an AI-based screening strategy is 8.6 times more effective at preventing vision loss than ECP, under base-case assumptions. No meaningful thresholds were found in one-way or two-way sensitivity analyses (See Table 2, supplementary Table 1 and supplementary Fig. 2 in Supplementary). The results of the two-way sensitivity analysis (supplementary Table 1) showed that across the broad range of sensitivity values AI dominated over ECP across all ranges for the following two-way comparisons: sensitivity and specificity of AI vs ECP screening, and accepting AI vs ECP screening. For the comparison regarding accepting referral after AI vs ECP screening, AI dominated except in the unlikely scenario of low probability of accepting referral after AI and a high probability of accepting referral after ECP. This scenario is far from the base-case, for further clarification, the output of this two-sensitivity analysis is shown in supplemental Fig. 3. In 2019, an estimated 37.3 million Americans had diabetes. If we use a conservative estimate of 30 million Americans with diabetes, based on the numbers above we anticipate that AI-based screening strategy is expected to prevent vision loss in over 27,000 more Americans at 5 years as compared to ECP-based strategy, under base-case assumptions.

Maximal scenarios

The scenario analyses show that, if adherence to recommended metabolic and ophthalmic treatment were maximized, the estimated total number with any vision loss at 5 years would be lower for both AI and ECP strategies when compared to the base case, with a higher reduction noted for the AI strategy. In the scenario that maximizes adherence to recommended treatment, the number with any vision loss by 5 years is estimated to be 1167/100,000 for the AI strategy, an additional reduction of 367/100,000 from the AI base case. In this scenario, the estimated total number with any vision loss for the ECP strategy instead is 1488/100,000, an additional reduction of 137/100,000 from the ECP base case. In all scenarios tested, the number with vision loss per 100,000 is lower with the AI strategy compared with the ECP strategy. Figure 1 shows the relative impact of increasing the probability of adhering with metabolic and ophthalmic treatments on projected vision loss for each screening strategy. Figure 2 shows the impact of maximizing diagnostic and process-of-care metrics on vision loss when using the AI screening strategy. The largest impacts are when adherence with recommended metabolic or ophthalmic treatments is maximized. The scenario with maximum adherence to metabolic treatment (100%) results in 110/100,000 fewer patients progressing to vision loss. The scenario with maximum adherence to ophthalmic treatment (100%), results in 294/100,000, fewer patients progressing, and maximizing both results in 367/100,000 fewer patients progressing. These numbers suggest an accretive effect of adherence to both metabolic and ophthalmic treatment. Using a conservative estimate of 30 million Americans with diabetes this translates into vision loss prevented in over 110,000 additional Americans with diabetes when AI-based screening is introduced, and treatment adherence is maximized. Maximizing the effectiveness of metabolic and ophthalmic treatments themselves, namely more effective drugs or procedures—does have a marginal impact of 25–28/100,000 fewer progressing, but this is only 6.8–7.6% of the benefit achieved by maximizing adherence to therapies that are currently available.

DISCUSSION

Using CAREVL, we conclude that autonomous AI is expected to be more effective than ECP-based screening at preventing vision loss among patients with diabetes. This effectiveness can be maximized by improving processes of care, particularly adherence with recommended treatments. Under base-case assumptions, introducing AI in a no-DRD-screening scenario is estimated to be 8.6 times more effective at preventing vision loss from DRD compared with introducing ECP-based screening. The expected

Table 2. One-way sensitivity analyses.

Population, diagnostic-accuracy, and process-of-care metrics	Type of metric	Base Case (minimum, maximum value for sensitivity analysis)[a]		Threshold[d]
		ECP	AI	
Prevalence of Metabolic DRD	Population	0.22 (0, 0.4)	0.22 (0,0.4)	AI dominates
Offered and accepts screening for DRD	Process of care	0.2 (0,0.8)	0.95 (0,1)	AI dominates
Sensitivity of the DRD screening strategy	Diagnostic accuracy	0.33 (0,1)	0.87 (0,1)	AI dominates
Specificity of DRD screening strategy	Diagnostic accuracy	0.99 (0,1)	0.91 (0,1)	AI dominates
Accepts referral for eye care after a positive screen	Process of care	0.29 (0,1)	0.75 (0, 0.95)	0.08[b]
Probability of adhering with treatment	Process of care	0.24 (0,1)	0.24 (0,1)	AI dominates
Effectiveness of ophthalmic treatments	Process of care	0.02 (0,0.5)	0.02 (0,0.5)	0.1[c]
Effectiveness of metabolic treatments	Process of care	0.01 (0,0.05)	0.01 (0,0.05)	AI dominates

DRD diabetic retinal disease, *ECP* eye care provider, *AI* artificial intelligence.
[a]The no-screening option is dominated by AI or ECP in all scenarios and has therefore not been included in this table.
[b]Far from base case value of 0.75.
[c] Far from base case value of 0.02.
[d]AI dominates refers to the finding that AI is the preferred strategy on each of the one-way sensitivity analyses (across the range of the minimum and maximum values for the parameter specified in parenthesis next to the base-case value).

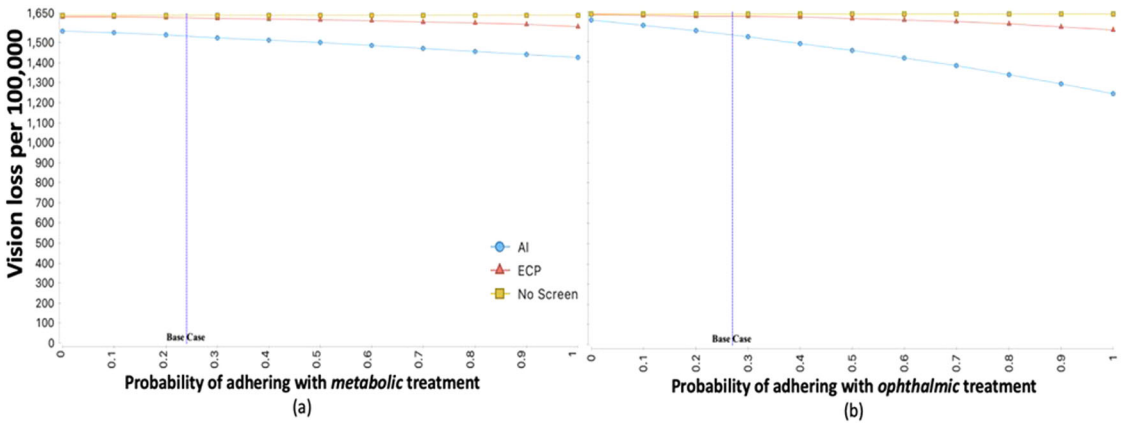

Fig. 1 Expected vision loss per 100,000 vs probability of adhering with treatment for each screening strategy. a, **b** Show that as the adherence with recommended metabolic and ophthalmic treatments increases the number of patients with vision loss per 100,000 decreases for both the eye care provider (ECP) and artificial intelligence (AI) screening strategies. However, the decrease in number with vision loss is more marked for the AI vs ECP screening strategy.

differences between ECP and autonomous AI screening strategies are likely due to a combination of factors. While the *efficacy* of AI screening systems in detecting referrable DRD has been established in prospective trials[11,13], the main drivers of higher *effectiveness* are likely the point-of-care availability of AI and immediate diagnostic output which make it more likely for a patient to accept screening and the recommended referral[4,14].

The CAREVL model is novel in that it allows evaluating the effectiveness of AI algorithms within the context of real-world patient workflow and the health-care system. Our approach is based on standards for performing and reporting modeling of expected impact of digital health technologies[7,15,16].Studies evaluating AI have traditionally focused on its diagnostic-accuracy metrics for a given task[11,17–19]. However, as we have shown, to evaluate the effectiveness of AI in the real-world we need to know not only its diagnostic accuracy or how it performs in controlled research settings, but its impact on patient outcomes[7]. This is important because many digital and non-digital health interventions may work well in an ideal 'model' setting, but real-world evaluation often reveals outcomes that are much less compelling compared to what can be achieved in a clinical trial setting[6,20–22].

The CAREVL model further allows us to study the expected impact of adjusting process-of-care metrics on patient outcomes and to identify which metrics may be most important in maximizing the effectiveness of AI within a health-care system, given a chosen strategy. This effort has immediate real-world implications for the implementation of AI-enabled patient-centered care. The CAREVL model suggests that the full potential of AI algorithms in preventing vision loss can be achieved by optimizing processes of care. Among the process-of-care metrics evaluated in the model, adherence with recommended metabolic and ophthalmic treatments had the largest impact on preventing vision loss. Prior studies such as the one by Rohan, et al., have estimated that screening and early treatment of DRD can prevent vision loss and reduce risk of blindness by an estimated 56%[23]. However, this estimate is predicated on perfect-world assumptions of 100% of patients accepting screening, high sensitivity of detecting referrable disease (88%), and 100% complying with recommended treatments. Real-world data from the US regarding adherence to metabolic management show that, on average, only

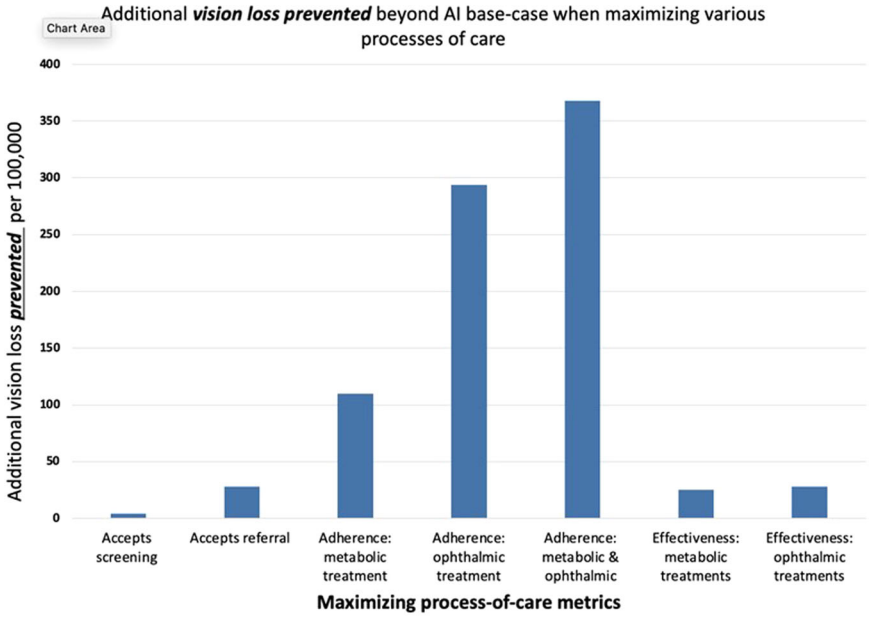

Fig. 2 Additional vision loss prevented beyond AI base-case when maximizing processes of care. Figure 2 shows the additional impact on vision loss prevented beyond the base-case scenario when each of the processes of care are maximized. The largest impact on vision loss is estimated to be from maximizing adherence with ophthalmic treatment, followed by adherence with metabolic treatments. Maximizing effectiveness of current metabolic and ophthalmic treatments has a lower impact.

about 22% of patients with diabetes achieve the recommended lipid, blood pressure and glucose control and only about 24% of patients with Type 2 DM achieve a glycated-hemoglobin level of <8%[24,25]. Adherence with recommended screening eye exams for DRD and follow-up eye care is similarly low[26]. Analysis of insured patients with diabetes showed that only about 15%[27] met the American Diabetes Association's recommendation for annual DRD screening and data from the National Health Interview Survey showed that only about a third of insured adults in the US followed up for eye care in the absence of visual impairment[28]. These low rates are concerning, as DRD is asymptomatic until late stages, hence the existence of Healthcare Effectiveness Data and Information Set (HEDIS) and Merit-based Incentive Payment System quality measures that incentivize diabetic retinal exams to be performed early and regularly[29].

The CAREVL model confirms that improving adherence with both the current metabolic and ophthalmic treatments is key to maximizing the success of implementing DRD screening strategies. The model suggests that when autonomous AI is used as a screening strategy, maximizing adherence with metabolic and ophthalmic treatments prevents vision loss in an additional 367 patients/100,000. This reduction is ~4 times more than just introducing AI without improving the process of care. While it remains important to develop increasingly effective treatments for metabolic and ophthalmic DRD, CAREVL suggests that its population impact on vision loss is much lower (~one-tenth) than that of maximizing adherence with existing treatments. This projected impact has important clinical and public health implications. Diabetes is a chronic disease that currently affects almost 37 million adults in the U.S[30,31], thus introducing AI-based screening could potentially prevent vision loss in an additional 27,000 patients with diabetes over the current ECP-based standard of care. Introducing AI and optimizing processes of care, particularly adherence with recommended treatment, could potentially prevent vision loss in an additional 110,000 patients. These benefits are expected to accrue as the prevalence of diabetes continues to rise. A more nuanced estimate would require further modeling to account for age distributions, annual incidence of diabetes and patient mortality.

The strength of our study is that we developed a real-world model, CAREVL, defining how to evaluate the effectiveness of an AI-based technology on patient outcomes. CAREVL is a relatively novel and more patient-centered approach to evaluating AI technologies as opposed to the overwhelming focus on evaluating diagnostic accuracy. Evaluating the impact of AI and digital health technologies on patient outcomes is an evolving area of research and we have made the model publicly available and invite others to contribute to it. The CAREVL model and this study have limitations. We relied on available, published and peer-reviewed data for the various metrics. It is important to collect real-world data over time, particularly with regards to ECP parameters, to further validate this model. This model does not address costs or utilities. As we are focused on effectiveness, we have considered vision loss in either eye. In future analyses focused on cost and disability benefits it may be better to consider vision loss in the worse seeing eye[32,33]. We did not compare the effectiveness of AI-based screening strategies with telemedicine programs as there is considerable variation between programs but once the relevant metrics identified in the model are collected, the relative effectiveness of telemedicine programs can be determined. One of the limitations of the study is that we did not model the benefit of ophthalmic encounters with an ECP as opposed to AI in potentially detecting diseases other than DRD (e.g., cataracts, macular degeneration, glaucoma). Our rationales for this decision were that (a) patients with visually significant cataract will have vision impairment (by definition) and will visit eye care instead of entering the screening pathway; (b) the number of potential missed cases is small: the pivotal trial that led to FDA approval of autonomous AI estimated that 0.2% of participants with glaucoma and 1.6% with non-exudative age-related macular degeneration may be missed by AI-based screening, no cases of neovascular age-related macular degeneration were noted[11]. Furthermore, the United States Preventive Services Task Force has determined that there is insufficient evidence to recommend screening for impaired vision from age-related changes such as age-related macular degeneration and glaucoma at this point[34,35]. We have analyzed the overall impact of autonomous AI in the US, and not the outcomes of specific

sub-groups within a population—these require more sophisticated models that we are currently developing. Nevertheless, we expect that CAREVL can be extended in well-established ways to help in answering questions regarding the impact of new technology on real-world outcomes from multiple perspectives (healthcare system, payor, or society).

In summary, our novel CAREVL model suggests that AI-based DRD screening is more effective at preventing vision loss from diabetes than ECP-based screening, and that this effectiveness can be further enhanced by optimizing processes of care. As use of digital health technology and AI increases in the healthcare system, this comprehensive model may serve as a framework for evaluating and estimating the real-world impact of digital technologies on patient outcomes in other chronic disease scenarios.

METHODS

Model structure

CAREVL is implemented as a computer-simulation based on a state-transition Markov model decision tree (one Markov model for each screening strategy). The model considers *population-metrics*, namely, community prevalence of the multiple severity stages of DRD, natural history of disease; *diagnostic-accuracy metrics* namely sensitivity and specificity; and *process-of-care metrics*, namely, the probability of accepting screening, of follow-up in case of a positive screen, of adherence with metabolic and ophthalmic management of DRD, and the effectiveness of metabolic and ophthalmic treatment. Figure 3 shows the states considered and the transitions between states permitted in the Markov model. The parameters of the model are probabilities and related quantities for states and transitions defined by the structure of the decision tree. The parameter values were derived from peer-reviewed published literature, and the base-case estimates are presented. Where choices for the base-case values were required, we biased the model against autonomous AI. Where relevant, the probabilities extracted from the literature were converted to transition probabilities[36]. The 12 model assumptions are detailed in the Supplementary. The models were built in TreeAge software (TreeAge Pro Healthcare version 2021 R1.1, Williamstown, MA), and we have made a spreadsheet version of the model available in the supplementary materials via Figshare (https://figshare.com/s/ad7809b8f7010fdf83c9). The parameters used in CAREVL are summarized in Table 1 and detailed in the Supplement. Fig. 3 shows the Markov-model structure used for each screening strategy. The full decision tree is in the Supplementary Fig. 1.

Target population

The target population is adults with Type 1 or 2 DM (age > 21 years) under regular care by a primary care physician, endocrinologist or other licensed provider. The base-case assumption of prevalence of DRD and its stages in primary care was estimated from a representative sample, as this population was drawn from adult patients with diabetes presenting to primary care settings with a racial and ethnic distribution that is representative of the 37 million people with diabetes in the US[11,30,31]. People with diabetes eligible for screening were categorized into three states: no DRD, metabolic DRD or ophthalmic DRD, defined as follows:

Fig. 3 Markov model showing the states and transitions relevant to diabetic retinal disease used in the current analysis. ❶Patients with diabetes mellitus presenting to the primary care or endocrine clinic with each of the following states: No Diabetic Retinal Disease, Metabolic Diabetic Retinal Disease, or Ophthalmic Diabetic Retinal Disease. ❷Natural history transitions of diabetic retinal disease. ❸Transitions from untreated to treated diabetic retinal disease. ❹Transitions of treated diabetic retinal disease. The transitions take into account process-of-care metrics i.e., probability of accepting screening and referral in case of a positive screen, probability of disease progression, probability of adhering with recommended treatments. The structure of the Markov model is the same for both screening strategies. Table 1 shows the base-case probabilities and limits of sensitivity analysis for each parameter that are specific to the AI and ECP screening strategies. The details of the transitions specific to each strategy are represented in the decision tree in the supplement (Fig. 3 is preserved and shared on Figshare (https://figshare.com/s/ad7809b8f7010fdf83c9).

mild, moderate and severe non-proliferative DRD (ETDRS levels 35–53) primarily require metabolic control and are categorized as "metabolic DRD"; "ophthalmic DRD" is defined as DRD requiring ophthalmic treatment in addition to metabolic treatment and is taken as equivalent to ETDRS level 60 and higher (i.e., proliferative diabetic retinopathy (PDR)) or having clinically significant macular edema or center-involved macular edema, without symptoms of vision loss. The prevalences of these states were varied in sensitivity analyses. Patients with known vision loss, are recommended to go directly for eye care as opposed to first going through a screening exam and were not included in the model[37,38].

Screening strategies

The CAREVL model is designed and built from the patient's perspective. Three alternative strategies for the diabetic eye exam were modeled: (1) no screening; (2) ECP strategy, where all patients are referred by the diabetes or primary care provider to an ophthalmologist or optometrist—referred to as ECP—for dilated diabetic eye exams in the clinic; (3) autonomous AI strategy, where the a digital fundus photograph is acquired and an autonomous artificial intelligence (AI) algorithm is used to analyze the image, real time result is provided, and only those diagnosed as having diabetic retinopathy or diabetic macular edema (DME) are referred for further management to ECP. The no-screening strategy was included to assess the relative impact of the other two screening strategies on expected visual outcome.

Main outcomes and measures

The model is focused on clinical outcome—any vision loss experienced by the patient. Specifically, outcome is quantified as the probability of severe vision loss by 5 years. Because of the established benefit of treatments for PDR and DME, today, it is impossible to ethically collect natural history outcome data on untreated PDR or DME. Therefore, we used the most recent data from landmark randomized clinical trials for treatment that still had natural-history arms for PDR and DME[39,40]. In these studies, severe vision loss was defined as worse than 5/200[39] and loss of 15 or more letters[40] on a standardized visual acuity chart. For visual outcomes of treated DME we used data from the anti-vascular endothelial growth factor (VEGF) treated arm of diabetic retinopathy clinical research network's protocol I[41], a landmark clinical trial which established the effectiveness of anti-VEGF agents for DME treatment. In that study, vision loss was defined as visual acuity of 20/200 or worse. Irreversible vision loss was the probability of visual acuity of 20/200 or worse at 2 years with or without treatment in either eye.

Sensitivity and scenario analyses

To evaluate the outcome under varying scenarios, and to account for uncertainty in base-case estimates, one-way sensitivity analyses were performed by varying one parameter at a time, while holding the others constant at their base-case estimates. Sensitivity analysis in decision analysis, to address uncertainty in model parameters, plays the same role as confidence intervals do in empirical statistical studies, to address uncertainty due to sampling. For those parameters that had different base-case values for AI vs ECP i.e., sensitivity and specificity of both strategies; accepting screening and accepting referral after screening, multiple two-way sensitivity analyses were conducted to determine if there were any scenarios where a strategy other than that identified in the base-case would be preferred. The relative impact of varying the values of key parameters on vision loss using either one of the screening strategies was evaluated. The key parameters included (1) population metrics; (2) diagnostic-accuracy metrics; (3) process-of-care metrics (see Table 1). We additionally created a series of maximal scenarios where individual parameters of process of care were set to each one's maximum value and assessed the marginal impact of each maximum scenario over the base-case dominant strategy. The goal of the maximal-scenario analysis was to estimate the potential impact of maximizing process-of-care metrics on expected vision loss.

The manuscript complies with the Consolidated Health Economic Evaluation Reporting Standards 2022 (CHEERS) checklist[15]; this checklist was chosen because, while ours is not an economic evaluation, this checklist comes closest to governing the type of study we present.

Reporting summary

Further information on research design is available in the Nature Research Reporting Summary linked to this article.

DATA AVAILABILITY

The online supplementary material includes a macro-enabled excel sheet that provides all data that were used to build the model.

CODE AVAILABILITY

The model was built using the TreeAge software. No separate code was written to run the Markov model.

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AUTHOR CONTRIBUTIONS

All authors (R.C., R.W., M.D.A., H.P.L.) contributed to the conception, design and writing of the paper. R.C. and H.P.L. performed the analysis of the study.

COMPETING INTERESTS

R.C.: none. R.W.: Research support Dexcom. M.D.A.: reports the following competing interests: Investor, Director, Consultant of Digital Diagnostics Inc, Coralville, IA; patents and patent applications assigned to the University of Iowa and Digital Diagnostics that are relevant to the subject matter of this paper. H.P.L.: None.

ADDITIONAL INFORMATION

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Statement of the American College of Surgeons
to the Committee on Energy & Commerce
Subcommittee on Health
United States House of Representatives
RE: Understanding How AI is Changing Health Care
November 29, 2023

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On behalf of the more than 88,000 members of the American College of Surgeons (ACS), we thank you for convening the hearing entitled "Understanding How AI is Changing Health Care." The ACS is dedicated to improving the care of the surgical patient and to safeguarding standards of care in an optimal and ethical practice environment. As such, we understand the critical role that technology plays in achieving this mission, as well as the need for thoughtful policymaking to ensure that tools such as artificial intelligence (AI) are used with the utmost regard for patients' rights and safety. As we discuss below, it is essential that AI tools are trained and maintained with high quality, diverse, valid, and representative data; are regularly assessed for continued accuracy and reliability; that regulators engage clinical experts in the assessment of AI health tools; and that physicians' clinical judgement remains paramount.

The ACS appreciates the House Energy & Commerce Health Subcommittee's attention to this critical issue and welcomes the opportunity to share some legislative and regulatory considerations for the use of AI in health care.

Ensuring Reliability Over Time

AI can be a powerful tool for medical innovation, but it is critical to ensure that these tools remain accurate and reliable as they develop. The ACS supports efforts to expand the use of real-world evidence (RWE) in the development and maintenance of medical technology. RWE is clinical evidence regarding the use and the potential benefits or risks of a medical product derived from analysis of real-world data (RWD), data related to a patient's health status or delivery of care that can be collected from a variety of sources such as mobile devices, wearables, and sensors; patient generated data used in home-use settings; product and disease registries; claims and billing activities; electronic health records, and more. Such data can complement data that are collected through traditional means and enhance clinical decision-making.

For the Food and Drug Administration (FDA) and other regulators, RWE is necessary for monitoring the safety of drugs, devices, and emerging technologies such as AI. As devices that use AI evolve, RWD will be reported back to the FDA regarding the product's safety, effectiveness, and potential risks. The true power of AI-based software lies in its ability to improve over time instead of remaining static. But this is problematic for regulation because the device that was approved or cleared may no longer be operating in a similar fashion as it learns. RWD is necessary to show that the AI-based device still functions appropriately and in the way that it was intended. RWD is also important for accurately training AI algorithms. These data should be high quality, diverse, valid, and representative of the uses for which it will be applied. Any regulatory framework should require that AI applications are assessed, maintained, and updated over their lifetime to ensure continued clinical safety and effectiveness, but also technological integrity. AI tools must be regularly reviewed to make sure they are still valid, reliable, and accurate as they learn.

AI health tools must be both (1) clinically and (2) technologically sound. Validity, reliability, and accuracy are required on both levels. The ACS believes that clinical experts, such as physician informaticists, are best positioned to determine whether data used in AI applications are the best quality and the most appropriate from a clinical perspective, and to monitor the technology for clinical validity as it evolves over time. The FDA should engage advisory groups for clinical and technical excellence that are conditionally or programmatically defined with cross specialty expertise, in order to ensure an AI tool is reliable and valid on multiple levels.

In addition, physicians and specialty societies are well-equipped to assist the FDA as they consider what tools and/or information would be most useful in driving improvements and advancements in clinical care

and the format in which the information should be expressed. Understanding where physicians see the benefits of AI in their practices is crucial to help build trust in the capabilities of the technology, leading to broader utilization. Likewise, understanding why physicians decide not to use or do not trust certain health technologies in their clinical practices would also be useful as regulators certify products for real-time use.

Validation of AI Health Tools

Validation of digital health tools, including AI applications, is truly essential to physician trust, improving care delivery, and avoiding patient harm. There are many aspects to validation. Validation is necessary in terms of the technology/algorithm used, the patient population on which the device is trained, whether the outcomes are accurate and unbiased, and whether the tool is appropriate for the specific setting in which it is used. While the FDA is responsible for regulating many digital health tools, the FDA should work in collaboration with an appropriate specialty society, clinical expert, or physician informaticist to reinforce physician trust in the tool. Use and validation of digital health tools are two of the most critical areas for physicians to successfully realize the potential of these technologies. In the case of AI tools, it is especially important to emphasize that the data used to train algorithms is critical to their validity and reliability. The data should be high quality, diverse, valid, and representative of the uses for which it will be applied. While the data used to train the AI-based tool is important, it is equally important that up-to-date data are used to retrain such tools so that the algorithms themselves remain current, reliable, and valid. Additionally, Congress could take steps to create a government-sponsored relationship with a synthetic patient environment, a free, open-source test bed that could be used to test the clinical and technical aspects of any AI application.

At the facility level, institutions should have their own governance and structure for AI-based tools, including pathways for user feedback and timely responses to feedback as physicians have concerns or encounter issues. Liability risks and uncertainty about who is responsible for issues with certain algorithms, outputs, or user errors can hinder implementation of these tools. Before leveraging AI technology, institutions should be confident in the quality of the tool and its capabilities.

Ultimately, digital health tools should reduce, not add to, a physician's cognitive burden. AI technology can enhance a physician's ability to gather, process, and exchange knowledge and ultimately improve patient care when the tool is developed using semantic data exchange standards in alignment with validated clinical workflows. This enables these tools to provide the right information at the right time and seamless incorporation into the clinical workflow.

Mitigating Bias

It is critical to consider bias when designing, training, and using AI health tools. Various forms of bias based on race, ethnicity, gender, sexual orientation, socioeconomic status, and more can be perpetuated through the use of certain advanced digital health tools, especially those using AI. Bias can manifest in digital tools in various ways. For instance, if an AI algorithm is trained with data that fails to include all patient populations for which the tool is used, this would introduce inherent bias. Bias could also be unintentionally written into algorithms, leading to outputs that could have a biased impact on certain populations. The context in which the tool is used should also be considered when trying to avoid bias. If the tool were trained on a certain population for a specific purpose and is applied in a different setting with a different patient population with varying risk factors, this could also result in bias.

While we will be unable to eliminate bias completely, steps can be taken to validate the quality of the data and reduce bias in AI algorithms. As discussed above, the need for trusted and complete data sources for AI tools is critically important, and ensuring the algorithms and data are properly validated is crucial. If the tool is not developed and trained with data that are representative of the patient population the physicians serve, the data outputs could be inaccurate or biased. To lower the risk of bias, the use of trusted and complete data sources in development and testing stages is extremely important. The data sources, methods of data collection, data quality, data completeness, whether the data are fit for purpose, and how the data are analyzed, must all be considered.

In addition, building a framework through collaboration with stakeholders possessing clinical and technical expertise that guides the development and validation of algorithms can assist in reducing bias if done with a high level of rigor. The framework could include a checklist with certain steps that developers would have to complete to ensure algorithms have gone through rigorous testing and validation. By following the processes and validation criteria set forth by the framework, developers can ensure that the algorithms are free of significant bias and will output accurate predictions. This type of framework coupled with external validation that utilizes data across various practice settings and demographics, can also be applied periodically following the implementation of the tool, to ensure that as the algorithms take in real-time data, they are still achieving a high-level of accuracy.

Safe and Appropriate Use

The FDA holds an important role in ensuring the safe and appropriate application of AI technology. Physicians can place greater trust in devices using digital technology if these devices have received FDA clearance or approval. FDA approval is also important for patient trust. Patients should know when they are receiving AI-informed care, and that it comes from validated instruments.

However, the ACS believes strongly that AI tools should never replace a physician's clinical judgment; rather, the goal of these and other digital health tools is to enhance physicians' knowledge and augment their cognitive efforts. Medical care relies not only on science, but on the capabilities of the care team, the local resources, and the goals of the patient. Care is highly personalized and requires a physician-patient interface where the medical knowledge is contextualized and personalized in a trusted manner for each patient and physicians are empowered to make clinical decisions. As we assess AI applications, part of the assessment must evaluate the insertion of AI knowledge artifacts into a human workflow. It is the AI application's utility in the workflow that makes a difference in the informed nature of care, in the diagnosis, and in the treatment.

Concluding Remarks

The ACS thanks the Energy & Commerce Health Subcommittee for convening this important hearing on understanding how AI is changing health care. In order to best serve patients and the physicians who care for them, it is essential that AI tools are trained and maintained with high quality, diverse, valid, and representative data; are regularly assessed for continued accuracy and reliability; that regulators engage clinical experts in the assessment of AI health tools; and that physicians' clinical judgement remains paramount. The ACS looks forward to continuing to work with lawmakers on these important issues. For questions or additional information, please contact Emma Zimmerman with the ACS Division of Advocacy and Health Policy at ezimmerman@facs.org.

November 29, 2023

The Honorable Cathy McMorris Rodgers
Chair
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The Honorable Frank Pallone
Ranking Member
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The Honorable Brett Guthrie
Chair, Subcommittee on Health
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The Honorable Anna Eshoo
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Re: Johnson & Johnson Statement for the Record for House Energy and Commerce Subcommittee on Health Hearing on Understanding How AI Is Changing Health Care

Dear Chair Rodgers, Chair Guthrie, Ranking Member Pallone, and Ranking Member Eshoo:

On behalf of Johnson & Johnson, we would like to thank you for holding the hearing titled "Understanding How AI is Changing Health Care." We commend the Committee for reviewing this transformative technology in the healthcare sector. We look forward to bipartisan action on this crucial issue for patients, health care providers, and innovators across the healthcare ecosystem.

Johnson & Johnson (J&J) is the world's largest and most diversified healthcare products company, and we are committed to using our reach and size for good. Innovation has been an essential part of the fabric of Johnson & Johnson for more than 135 years. Thanks to the incredible efforts of tens of thousands of scientists, researchers, engineers, designers, and clinicians, we have pioneered multiple breakthroughs to profoundly change the trajectory of health for humanity.

Artificial intelligence (AI) and machine learning play an increasingly important role in delivering excellence at Johnson & Johnson. AI is helping to drive socially beneficial innovations and new ways of helping those we serve live healthier lives. For instance, it is used in drug development, robotic-assisted surgery, commercial activities, chatbots and smart manufacturing in our supply chain. We are applying AI across our business, focusing on finding solutions to big questions and advancing our impact on patients. We believe AI, when used at scale, has the potential to accelerate our ability to advance human health. AI allows us to analyze larger-than-ever data sets in ways never before possible to find patterns and trends that are helping to transform our innovation engine. Through AI and data science, we can better understand the drivers of diseases, transform how we innovate to create treatments, design more personalized healthcare for patients, and deliver efficiency and precision for clinicians and surgeons to improve medical outcomes.

The use of AI in healthcare needs to be built on a foundation of trust. To provide clarity and certainty in the development and deployment of AI, we believe that any framework should leverage risk-based mechanisms and existing research and ethics standards, practices, and guidelines. Consideration of new regulation should begin with an assessment of existing

authorities and regulatory systems that can be adapted and applied to AI. We encourage a whole of government approach that looks across agencies and branches to maximize coordination, avoid redundancies, and streamline efforts to harness the enormous potential of AI.

Supporting Medical Innovation

Any policy regarding AI should have a clear scope and framework, facilitating implementation and avoiding complexity, to build trust between citizens, developers, deployers and users and create a favorable environment that fosters medical innovation. Policy development should begin with an assessment of existing policies and regulations, including applicable sector-specific laws and guidelines, such as the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Highly regulated sectors, like the healthcare industry, have existing frameworks for addressing relevant risks (e.g., safety, security, privacy), and these frameworks should be evaluated for their contribution and applicability to AI.

Recognizing the accelerated speed of AI continuous development, it is crucial to promote consensus-based standardization to assure a thriving and innovative ecosystem, avoiding a fragmented system that could hinder investment in innovation in the long term. Regulatory efforts should focus on a risk-based approach, a transparent framework for compliance and enforcement and versality of regulation to promote innovation with the aim to pursue fair, responsible, secure, and transparent use of AI.

As AI and machine learning are increasingly used in healthcare (e.g., drug development, robotic assisted surgery, smart manufacturing, etc.), there is opportunity to provide additional clarity on existing regulations. It is essential that innovators and developers know as early as possible the information, for example metrics and endpoints, that document the development and performance of AI/ML models will be required by regulators to approve and/or license an AI model. It is also important to establish monitoring processes, as ongoing assessment of usage of AI models is key to assure transparency, accountability, safety, and interpretability. Some examples of use cases for which additional clarification could be beneficial include:

- Instances where predictions are being made about patients that may influence their subsequent treatment, cases such a medical decision support, prediction of future events, risk prediction, AI/ML as medical devices and use within medical devices.
- Deployment of AI/ML in clinical practice.
- Potential use of AI to support molecular discovery efforts to predict the clinical performance of a drug in development.
- Use of AI/ML models for patient selection, stratification, and endpoint evaluation, which may have potential to directly impact patient care and labeling claims.

Ethics in AI and Protecting Patients

We believe ethical considerations should be at the forefront of how we are applying AI models and that regulation has a key role to promote the responsible and transparent usage of AI. Well-established practices and standards exist for demonstrating clinical validity and utility and

connecting these efforts to meaningful outcomes for patients[1]. It is important to start by assessing the existing research practices used for creation of treatment guidelines and approvals of new therapies to assess any AI-related gaps.

- Although AI/ML developers are developing methodologies and good practices for bias identification and management, regulators should be at the forefront of assuring AI decision making is following an agreed-upon set of social values and not perpetuating biases. It will be critical to address the propensity of AI applications to express bias based on the data on which they are trained, especially in the health care space where disparities in health outcomes are a disappointingly persistent reality.
- Diversity, equity and inclusion must be considered in all aspects of AI (e.g., selecting the issues to address/problems to solve using AI, training and hiring a diverse workforce from the data scientists to programmers, attorneys, and program managers).
- Not all data is created equal, and data that is not reflective of the population it intends to help or the unbiased problem it intends to solve does not have the proper level of quality upon which society can rely. Fostering participation by diverse populations will help enable data generation that simultaneously improves the authenticity of data sets and the inclusivity of data-driven insights.
- AI systems must continually be monitored, and models must be adjusted for fitness for purpose, accuracy and resilience, in addition to monitoring and testing datasets for accuracy and to avoid unfair bias.

Stakeholders are currently utilizing certain practices to help assure the integrity of AI/ML or to address issues such as bias, missing data, and other data quality considerations. Any frameworks should consider existing standards of conduct and practices, such as:

- Investigating the source of missingness, ensuring models are tested on representative and diverse populations, thorough review of features used in modelling.
- Testing model performance on patient subpopulations, understanding the data ingestion/data structuring process used for ML methodology.
- Development and implementation of Post-Training Fairness metrics and assessments and constant monitoring of deployed ML solutions to detect drift.
- Development of methods to aid interpretability and transparency.
- Contrast and comparison with more traditional approaches and previous scientific research.
- Incorporating Human in the Loop (HITL) workflows.

Data as an Enabler of AI

Another key element for safe, ethical, and transparent AI use is privacy. We operate in a highly regulated industry where we use a variety of types of data, including administrative and claims data, clinical data, genomic data, patient-generated data, and social determinants of health data that move through a variety of transmission networks. This data is essential to continued innovation, discovery, evaluation, and speed for the delivery of healthcare products and services to patients and consumers. We use data to enable greater precision in medicine,

[1] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7909857/

expand the range and application of effective therapies, and empower and support patients. It serves a critical role in new and innovative healthcare models by flagging potential safety concerns, promoting adherence to treatment, personalizing care, or connecting an extended healthcare and support team. Many of these innovations can also contribute to overall lower costs for healthcare.

Innovation in the healthcare industry and effective treatment of patients are heavily dependent on appropriate access to, and use of, patient and consumer data. We support adoption of a comprehensive national privacy law and associated standards to help ensure a more consumer- and patient friendly approach to managing personal information while ensuring consistent privacy protections, reducing variability across multiple governments and government agencies, allowing a greater flow of data, and maintaining adequate protections.

Workforce and Digital Literacy in AI

Healthcare professionals need to have a thorough understanding of digital technologies for healthcare systems to effectively guide patients. We support policies to empower and diversify both the data science and provider workforce, support educational advancement, and drive access to the full range of healthcare providers to reduce health inequities and ensure that all have access to innovations, such as:

- Training diverse healthcare professionals to read, analyze, and interpret data is essential to increase efficiency of care, achieve better outcomes, increase equity, and help patients understand and consider their care options. Healthcare workforce planning and education are important tools for policymakers to anticipate future skills shortages and take remedial action in education and training policies early on.
- Diversifying the AI and technology workforce and increasing training in the field for underrepresented minorities is critical for bias reduction and inclusivity in data ecosystems. We also need more life science education and training programs to improve the application and customization of technologies like AI to healthcare needs.
- Digital access and literacy are critical to ensure citizens and patients are empowered to manage their own data, understand the benefits of AI, and have the tools to make informed decisions.
- Workforce skilling via lifelong learning programs and university education, equipping the workforce with the reskilling and continued learning opportunities required to embrace ongoing technological developments to maximize the positive impact of AI. For example, investments to enhance the digital skills of healthcare professionals (HCPs) could be done through pre-certification by medical societies and advancement of AI curricula for both HCPs and hospital managers.

If we include healthcare workers as a critical group when designing, deploying, and assessing AI solutions, and have broad, sustainable funding from government, we can use AI to support the healthcare workforce, including their work experience and resiliency, and improve outcomes for all members of the ecosystem.

Conclusion

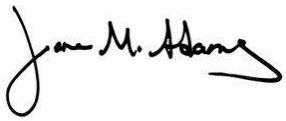
We recognize the power and promise of AI in healthcare and believe this is a collective effort. We value our role as collaborator and innovator in healthcare, contributing new ideas, solutions, technology, partnerships, and perspectives on AI policy. We are focused on increasing engagement and cocreation with patients, providers, and policymakers to raise the understanding on how harnessing the potential of AI in healthcare can help everyone.

***

J&J looks forward to serving as a resource and providing additional thoughts about policies to assure AI is ethically, safely, and efficiently integrated into our society. Thank you for your attention to this critically important issue. If you have any questions or we can provide any assistance to the Committee, please email Leif Brierley at LBrierl1@its.jnj.com.

Sincerely,

Jane M. Adams
Vice President, Federal Affairs



Andrea Masciale
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PREMIER TRANSFORMING HEALTHCARE TOGETHER®

November 29, 2023

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Re: Understanding How AI is Changing Health Care

Dear Chair Rodgers, Ranking Member Pallone, Chairman Guthrie and Ranking Member Eshoo:

On behalf of Premier Inc. and the providers we serve, we thank you for your commitment to examining the ways in which technology can be leveraged in healthcare to improve efficiency and patient care, drive innovation and develop innovative therapies. Premier appreciates the opportunity to share our recommendations and insights related to the role of artificial intelligence (AI) and looks forward to working with Congress on these issues.

Premier has thought critically about the potential legislative and regulatory framework for AI in healthcare and recently published an Advocacy Roadmap for AI in Healthcare.[1] ***While Premier believes that AI can and should play a critical role in advancing healthcare and spurring innovation, Premier also believes that AI cannot and should not replace the practice of medicine.***

Additional detailed comments and recommendations, based on our depth of experience in using AI in healthcare, are included below.

I. BACKGROUND ON PREMIER INC.

Premier is a leading healthcare improvement company, uniting an alliance of more than 4,350 U.S. hospitals and approximately 300,000 continuum of care providers to transform healthcare. With integrated data and analytics, collaboratives, supply chain solutions, consulting and other services, Premier enables better care and outcomes at a lower cost. Premier plays a critical role in the rapidly evolving healthcare industry, collaborating with members to co-develop long-term innovations that reinvent and improve the way care is delivered to patients nationwide. Headquartered in Charlotte, N.C., Premier is passionate about transforming American healthcare.

Premier is already leveraging AI to move the needle on cost and quality in healthcare, including:

- Stanson Health, a subsidiary of Premier, designs technology to reduce low-value and unnecessary care. Stanson leverages real-time alerts and relevant analytics to guide and influence physician's decisions through clinical decision support technology, providing higher-quality, lower-cost

[1] See appendix for Premier's Advocacy Roadmap for AI in Healthcare.

healthcare. Stanson's mission is to measurably improve the quality and safety of patient care while reducing the cost of care by enabling context-specific information integrated into the provider workflow.

- Premier's PINC AI™ Applied Sciences (PAS) is a trusted leader in accelerating healthcare improvement through services, data, and scalable solutions, spanning the continuum of care and enabling sustainable innovation and rigorous research. These services and real-world data are valuable resources for the pharmaceutical, device and diagnostic industries, academia, federal and national healthcare agencies, as well as hospitals and health systems. Since 2000, PAS researchers have produced more than 1,000 publications which appear in 264 scholarly, peer-reviewed journals, covering a wide variety of topics such as population-based analyses of drugs, devices, treatments, disease states, epidemiology, resource utilization, healthcare economics and clinical outcomes.

- Conductiv, a Premier purchased services subsidiary, harnesses AI to help hospitals and health systems streamline contract negotiations, benchmark service providers and manage spend based on historical supply chain data. Conductiv also works to enable a healthy, competitive services market by creating new opportunities for smaller, diverse suppliers and helping hospitals invest locally across many different categories of their business.

II. PROTECTING PATIENT RIGHTS, SAFETY AND NATIONAL SECURITY

Premier supports the responsible development and implementation of AI tools across all segments of American industry – particularly in the healthcare industry - where numerous applications of this technology are already improving patient outcomes and provider efficiency. Premier sees a defined role for Congress in advancing clear statutory guidelines that will allow providers and payers to deploy AI technology to its full potential, while still protecting individual rights and safety.

Premier strongly supports AI policy guardrails that include standards around transparency and trust, bias and discrimination, risk and safety, and data use and privacy.

PROMOTING TRANSPARENCY

Trust – among patients, providers, payers and suppliers – is critical to the development and deployment of AI tools in healthcare settings. To earn trust, AI tools must have an established standard of transparency. Recent policy proposals, including those proffered by the Office of the National Coordinator for Health Information Technology (ONC), suggest transparency can be achieved through a "nutrition label" model. This approach seeks to demystify the black box of an AI algorithm by listing the sources and classes of data used to train the algorithm. Unfortunately, some versions of the "nutrition label" approach to AI transparency fail to acknowledge that when an AI tool is trained on a large, complex dataset, and is by design intended to evolve and learn, the initial static inputs captured by a label do not provide accurate insights into an ever-changing AI tool. Further, overly-intrusive disclosure requirements around data inputs or algorithmic processes could force AI developers to publicly disclose intellectual property or proprietary technology, which would stifle innovation.

Premier recommends that AI technology in healthcare should be held to a standardized, outcomes-focused set of metrics, such as accuracy, bias, false positives, inference risks, recommended use and other similarly well-defined values. Outcomes, rather than inputs, are where AI technologies hold potential to drive health or harm. Thus, Premier believes it is essential to focus transparency efforts on the accuracy, reliability and overall appropriateness of AI technology outputs in healthcare to ensure that the evolving tool does not produce harm.

MITIGATING RISKS

It is important to acknowledge potential concerns around biased or discriminatory outcomes resulting from the use of AI tools in healthcare, as well as potential concerns around patient safety. Fortunately, there are several best practices that Premier and others at the forefront of technology are already following to mitigate these risks. First, we reiterate Premier's recommendation for standardized, outcomes-based assessments of AI technologies' performance, which would ***hold AI developers and vendors responsible for monitoring for any biased outcomes***. Performance reporting could incorporate results from disparity testing before and after technology deployment to ensure that bias stays out of the AI "machinery."

Premier also supports the development of a standardized risk assessment, drawing on the extensive groundwork already laid by the National Institute of Standards and Technology (NIST) in the AI Risk Management Framework. An AI risk assessment should identify potential risks that the AI tool could introduce, potential mitigation strategies, detailed explanations of recommended uses for the tool and risks that could arise should the tool be used inappropriately. Premier urges Congress to consider a nuanced approach to risk level classification for the use of AI tools in healthcare. While there are some clinical applications of AI technology that could be considered high risk, it is certainly true that not all healthcare use cases carry the same level of risk. For example, the use of AI technology to reduce administrative burden or improve workflow in a hospital carries a much different level of risk and very different safety considerations than the use of AI technology to make clinical decisions and treat patients. Premier also supports the development of standardized intended use certifications or reporting requirements for AI technologies, which would prevent new systems from producing harmful outcomes due to use outside of the technology's design.

Finally, Premier understands the importance of data standards, responsible data use and data privacy in the development and deployment of AI technology. Data standards should specifically focus on objective assessment of potential sources of bias or inaccuracy introduced through poor dataset construction, cleaning or use. These may include, but are not limited to, appropriately representative datasets, bias in data collection (e.g., subjectivity in clinical reports) or introduced by instrument performance or sensitivity (e.g., pulse oximetry devices producing inaccurate measurements of blood oxygen levels in patients with darker skin), bias introduced during curation (e.g., datasets with systemically introduced nulls and their correlation, such as failure to pursue treatment due to lack of ability to pay), and training and test data that is appropriately applicable to various patient subpopulations (e.g., data that sufficiently represents symptoms or characteristics of a condition for each age/gender/race of patient that the tool will be used to treat). Premier also supports the establishment of guidelines for proper data collection, storage and use that protect patient rights and safety. This is particularly important given the sensitivity of health data.

III. DRUG RESEARCH, DEVELOPMENT AND MANUFACTURING

One critical area where Premier would highlight the transformative potential of AI is drug research, development and production. Congress and the Administration must work collaboratively to pre-empt uncertainty and responsibly govern the deployment of emerging technologies in these areas in a patient-centered manner. Premier specifically recommends timely legislative and/or regulatory guidance for the use of AI in clinical trials and drug manufacturing.

OPPORTUNITIES FOR AI IN CLINICAL TRIALS

Premier sees particular promise for the use of AI in streamlining processes and expanding patient access in clinical trials.

Identifying trial participants: One of the biggest challenges facing health systems that seek to participate in or enroll patients in clinical trials is identifying and enrolling patients in a timely manner. Delays in meeting trial enrollment targets and timelines can increase the cost of the trial. AI tools have the ability to analyze

the extensive universe of data available to healthcare systems in order to identify patients that may be a match for clinical trials that are currently recruiting. This application of natural language processing systems can make developing new drugs less expensive and more efficient, while also improving patient and geographical diversity in trials to address health equity.

Generating synthetic data: AI, once trained on real-world data (RWD), has the capability to generate synthetic data and patient profiles that share characteristics with the target patient population for a clinical trial. This synthetic data can be used to simulate clinical trials to optimize trial designs, model the possible effects or range of results of a novel intervention, and predict the statistical significance and magnitude of effects or biases. Ultimately, synthetic patient data can help optimize trial design, improve safety and reduce cost for decentralized clinical trials. Further, synthetic control arms in clinical trials can help increase trial enrollment by easing patient fears that they will receive a placebo or standard of care. To encourage continued innovation, clear guidance is needed from Congress and/or the Food and Drug Administration (FDA) on the process for properly obtaining consent from patients for the use of their RWD to produce AI-generated synthetic control arms in clinical trials.

OPPORTUNITIES FOR AI IN DRUG MANUFACTURING

Premier sees potential for AI to transform at least three key segments of the drug manufacturing process: supply chain visibility, advanced process control, and quality monitoring.

Supply chain visibility: Premier believes the application of AI can advance national security by helping build a more efficient and resilient healthcare supply chain. Specifically, AI can enable better demand forecasting for products and services, such as drug components, through analysis of historical and emerging clinical and patient data. As the COVID-19 pandemic demonstrated, the ability to understand and react to shortages poses a critical challenge to healthcare providers; AI enables better planning and response time to national or regional emergencies. AI can drive better inventory management by automating the monitoring and replenishment of inventory levels. Healthcare providers can leverage AI to better manage suppliers through faster more efficient contracting processes and by monitoring of supplier key performance metrics. As Premier works to combat drug shortages, the most effective remedies begin with supply chain visibility and reliable predictions that allow manufacturers to plan for and respond to shortages or disruptions – this crucial element of the drug manufacturing process presents a key value-add opportunity for AI technology.

Advanced process control: Another significant value-add for AI in the drug manufacturing process is in the development and optimization of advanced process control systems (APCs). Process controls typically regulate conditions during the manufacturing process, such as temperature, pressure, feedback and speed. However, a recent report found that industrial process controls are overwhelmingly still manually regulated, and less than 10 percent of automated APCs are active, optimized and achieving the desired objective. These technologies are now ready to transform drug manufacturing on a commercial scale; however, challenges still remain to widespread adoption. Premier strongly believes that the FDA should issue clear guidance that supports the industry-wide transition to AI-powered APCs. Such technologies offer drug manufacturers the opportunity to assess the entire set of input variables and the effect of each on system performance and product quality, automating plant-wide optimization. This application of AI technology can transform the physical manufacturing of drugs and pharmaceuticals, leading to cost-savings and increased resiliency, transparency and safety in the drug supply chain.

Quality monitoring: AI can also provide value-add to drug manufacturing in the field of quality monitoring and reporting. Current manufacturing processes provide an immense volume of data from imagers and sensors that, if processed and analyzed more quickly and efficiently, could transform approaches to safety and quality control. AI models trained on this data can be used to predict malfunctions or adverse events. AI can also perform advanced quality control and inspection tasks, using data feeds to quickly identify and correct product defects or catch quality issues with products on the manufacturing line. Taken together, these capabilities can improve both the accuracy and speed of inspections and quality control, helping

companies to reliably meet regulatory requirements and avoid costly delays that disrupt the drug supply chain.

IV. TRAINING THE HEALTHCARE WORKFORCE OF THE FUTURE

Premier believes technology can and should work alongside and learn from healthcare professionals, ***but current technology will not and should not replace the healthcare workforce.***

To ensure clinical validity and protect patients, Premier reiterates the importance of comprehensive risk assessments, recommended use, and trainings that combat automation bias and incorporate human decision-making into the use of AI technology in healthcare. The risks and safety concerns around AI technology are unique to each use case, and Premier supports the requirement of a risk assessment and mitigation plan specific to the level of risk associated with the use case. Premier also supports the development of standardized intended use certifications or reporting requirements for AI technologies, which would prevent new systems from producing harmful outcomes due to use outside of the technology's design.

Premier acknowledges the risks of automation bias and fully automated decision-making processes. To reduce these risks, promote trust in AI technologies used in healthcare and achieve the goal of supporting the healthcare workforce through AI, ***Premier recommends that healthcare workforce training programs provide comprehensive AI literacy training***. Healthcare workers deal with high volumes of incredibly nuanced data, research and instructions – a growing percentage of which may be supplied by AI. This is particularly true for applications of AI in drug development, where manufacturers and quality control specialists may be reviewing high volumes of AI-powered recommendations or insights and making rapid decisions that affect the safety of patients. By ensuring our healthcare workers understand how to evaluate the most appropriate AI use cases and appropriate procedures for evaluating the accuracy or validity of AI recommendations, we can maximize the advisory benefit of AI while mitigating the risk to patients and provider liability. Additionally, clear, risk-based guidance on which uses of AI technology in healthcare require human review and decision-making is essential.

Additionally, watermarking or provenance data/systems for AI-generated content were a component of the voluntary commitments recently announced by the Administration. Premier generally supports the development of similar metrics for scientific research or clinical decision support recommendations produced by AI technology. It is important that patients, scientists, drug manufacturers and medical professionals understand when decisions or recommendations are made by AI so they can consciously respond and evaluate the new information accordingly.

Specifically, watermarking is one potential strategy to combat automation bias, a risk especially pertinent to the use of AI technology in healthcare. Automation bias refers to human overreliance on suggestions made by automated technology, such as an AI device. This tendency is often amplified in high-pressure settings that require a rapid decision. The issue of automation bias in a healthcare setting is discussed at length by the FDA in guidance on determining if a clinical decision support tool should be considered a medical device. Premier suggests that future guidance or standards for the use of AI should consider automation bias in risk assessments and implementation practices, such as workforce education and institutional controls, to minimize the potential harm that automation bias could have on patients and vulnerable populations, including to mitigate any potential risk of AI used in unintended settings or built on biased datasets. In the drug manufacturing process, it is important that workers evaluating a supply chain disruption prediction, optimization recommendation, or quality control report know that the data or recommendation is AI-generated and evaluate it effectively.

V. CONCLUSION

In closing, Premier appreciates the opportunity to share comments on the topic of AI and its role in healthcare. If you have any questions regarding our comments, or if Premier can serve as a resource on these issues to the Subcommittee in its policy development, please contact Mason Ingram, Director of Payer Policy, at Mason_Ingram@premierinc.com or 334-318-5016.

Sincerely,

Soumi Saha, PharmD, JD
Senior Vice President of Government Affairs
Premier Inc.

PREMIER®

PREMIER'S ADVOCACY ROADMAP FOR THE 118TH CONGRESS: ARTIFICIAL INTELLIGENCE IN HEALTHCARE

Premier supports the responsible development and implementation of artificial intelligence (AI) tools across the healthcare industry, where AI is already demonstrating its ability to help improve patient outcomes and provider efficiency. AI holds great potential for empowering the healthcare workforce, mitigating supply chain shortages, advancing health equity and driving higher-quality care. While Premier embraces AI's potential, we also acknowledge that trust – among patients, providers, payers, policymakers and suppliers – is critical for the responsible adoption of AI tools in healthcare settings. To earn trust, AI tools must be subject to clear statutory, regulatory and subregulatory guidelines that ensure transparency and protect individual rights and safety.

While Premier believes that AI can and should play a critical role in advancing healthcare and spurring innovation, Premier also believes that AI cannot and should not replace the practice of medicine.

OPTIMIZING THE VALUE OF HEALTHCARE

Providers, both acute and non-acute, continue to experience significant fiscal challenges stemming from a combination of increased labor costs, record inflation and lagging reimbursement rates that do not account for these unprecedented financial challenges.

Promote the use of AI in value-based care to amplify delivery system transformation. AI tools hold immense potential for identifying the highest-risk patient populations, as well as the best ways to deploy clinical resources to serve them. Innovative payment models allow resource flexibility to invest in technology such as AI to shift the paradigm of population health management.

Advance the use of AI in healthcare quality programs and measurement. Providers, payers and the federal government can all benefit from technology resources that look deeper than descriptive data. Premier will continue to work with our federal partners to demonstrate transformative use cases for AI in Medicare and other quality programs.

Create opportunities for AI to support the overburdened healthcare workforce. Premier will advocate for federal healthcare workforce programs that leverage AI to identify root causes of healthcare workforce shortage and train the clinical workforce on how to best leverage AI technology to optimize workflows and patient care.

BUILDING RESILIENT HEALTHCARE SUPPLY CHAINS

Premier advocates for policies that create visibility and transparency into the healthcare supply chain. Premier's goal is to ensure that every provider in the country has access to the right product, at the right time, at the right quality and at the right price for patient care.

Advance the use of AI to provide visibility into drug and medical supply chains. Premier will advocate for federal programs and financial incentives to increase the use of AI for medical supply chain insights, including the source of raw materials, to enhance national security and preparedness.

Provide AI-driven insights to build resilient supply chains. Premier will operationalize AI insights to inform federal policymaking and preparedness while bolstering supply chain resiliency, including strengthening supply chain integrity.
Leverage AI-driven tools to predict drug and device shortages. Premier will operationalize AI insights to inform federal policymaking related to drug and device shortages, including opportunities for the Food and Drug Administration (FDA) to leverage private sector AI algorithms to proactively predict shortages.

Incorporate AI into advanced manufacturing techniques. Premier will advocate for policies that support the incorporation of AI into advanced manufacturing techniques to support diversification of supply chains and manufacturing resiliency.

TECH-ENABLING HEALTHCARE

Premier advocates for policies to advance technology that will enhance patient safety and quality improvement, facilitate secure and timely communication and data exchange among healthcare stakeholders, and produce actionable and reportable data.

Improve trust and transparency for healthcare AI solutions. Premier will pursue trustworthy AI standards, including transparency in algorithmic decision-making, focusing accountability on the outputs and outcomes of AI technology.

Encourage AI innovation and competition. Premier will work with government partners to encourage policies that promote innovation in AI and the ability of U.S. companies to compete with international counterparts.

Support the use of clinical decision support technology. Premier will advocate for federal policies that advance the adoption of clinical decision support technologies, including continued support for accelerated approvals for physician-developed tools.

ELIMINATING GAPS IN HEALTHCARE

Premier advocates for policies that address the disparities in access to and quality of healthcare experienced by vulnerable communities and populations.

Support innovation in clinical trial recruitment and operations, ensuring all populations have access to breakthrough medical technology. Premier will work with the FDA to ensure clear and consistent guidance allowing for innovative uses of AI to identify and recruit patients for trials, construct control arms using real-world data, and develop synthetic data to improve trial design and safety.

Support the incorporation of novel digital endpoints into clinical trials. Premier will work with the FDA and industry partners to find ways to harness the analytical power of AI to incorporate novel digital endpoints and previously unavailable inferences into clinical trials, strengthening evidence available about new drugs and devices.

Prevent bias from hindering AI's effectiveness. Premier will work across government and industry to incorporate standards and regulations designed to detect and prevent bias in AI systems, including data standards, ongoing disparity testing, quality controls and outcome monitoring, and a risk-based framework for AI deployment in healthcare.

Click here to download Premier's Advocacy Roadmap.

For more information on Premier's advocacy agenda, please contact:
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November 29, 2023

Dear Chair McMorris Rodgers, Ranking Member Pallone, Chairman Guthrie, and Ranking Member Eshoo:

In advance of this week's Subcommittee on Health hearing titled "Understanding How AI is Changing Health Care," I am writing to reiterate TechNet's support for efforts to ensure any artificial intelligence (AI) policies benefit all Americans, address the risks, and strengthen our global competitiveness.

TechNet is the national, bipartisan network of technology CEOs and senior executives that promotes the growth of the innovation economy by advocating a targeted policy agenda at the federal and 50-state level. TechNet's diverse membership includes dynamic American businesses ranging from startups to the most iconic companies on the planet and represents over 4.2 million employees and countless customers in the fields of information technology, artificial intelligence, e-commerce, the sharing and gig economies, advanced energy, transportation, cybersecurity, venture capital, and finance.

AI is a transformational technology that has the potential to revolutionize how we live and work and help us solve the most significant challenges of our time. AI can enhance productivity, democratize and expand access to important services, and improve product innovation. TechNet members represent many of the leading AI and automated systems developers, researchers, deployers, and users.

We believe that harnessing the power of innovation, including AI, is a critical step in advancing our healthcare system. The adoption of modern technologies can help improve healthcare delivery and outcomes. AI is already being used to increase productivity and transform healthcare professional and patient experiences. According to Accenture, the accelerated adoption of data and analytics capabilities to fuel decisions and operations is a top investment priority for a majority of life sciences companies.

AI is enhancing diagnostics and disease prediction and accelerating the development of new medical treatments, including life-saving vaccines and ways to detect earlier signs of cancer. Moderna used AI to develop a COVID-19 vaccine in record time,[1] and researchers at MIT are using AI to create antibiotics that could

[1] Me, Myself, and AI. "AI and the COVID-19: Moderna's Dave Johnson." July 13, 2021. https://sloanreview.mit.edu/audio/ai-and-the-covid-19-vaccine-modernas-dave-johnson/.

combat drug-resistant infections.[2] AI is saving lives by reducing brain scan review time from five hours to 30 seconds,[3] making accurate predictions about disease-causing DNA mutations,[4] and allowing for the creation of special, individualized medical devices in a matter of hours instead of months.[5] It is also improving lives by helping underrepresented populations access clinical trials[6] and providing blind people with new and powerful visual interpretation tools that allow them to be more independent and live fuller lives.[7]

AI has the potential to transform healthcare to the benefit of all Americans. However, recognizing and addressing the genuine risks associated with AI is crucial for its responsible development. It is important to note that AI technologies are governed by existing law. However, policymakers can support AI innovation and address risks through careful policymaking.

To aid in this effort, on October 27, TechNet released a comprehensive federal framework on the policies needed to address AI risks while allowing the United States to maintain its global AI leadership. This framework comprises five distinct sections, each addressing key facets of the evolving AI ecosystem that are applicable across all industries. From deploying risk-based regulations to fostering responsible AI evaluations, mitigating potential bias, securing advanced systems, and building a resilient innovation workforce, our recommendations are the result of collective expertise and a commitment to shaping a forward-looking, prosperous future for our nation.

We thank you for your commitment to advancing the responsible development and deployment of AI to improve the efficiency and overall effectiveness of America's healthcare system, and we look forward to working with you on this important issue. Please don't hesitate to reach out if we can be a resource on this issue or if you have any questions. I can be reached at cholshouser@technet.org or (210) 286-6276.

Sincerely,

Carl Holshouser

Carl Holshouser
Executive Vice President

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[2] Trafton, Anne. "Using AI, Scientists Find a Drug that Could Combat Drug-resistant Infections." May 25, 2023. https://news.mit.edu/2023/using-ai-scientists-combat-drug-resistant-infections-0525#:~:text=A%20novel%20mechanism,strains%20isolated%20from%20human%20patients.
[3] https://cloud.google.com/customers/jhu-bios
[4] https://www.deepmind.com/blog/alphamissense-catalogue-of-genetic-mutations-to-help-pinpoint-the-cause-of-diseases
[5] https://pratt.duke.edu/news/ventilator-splitter/
[6] https://ai.meta.com/blog/open-sourcing-a-new-parser-to-improve-clinical-trial-participant-recruitment/
[7] https://ai.meta.com/blog/ai-predicts-effective-drug-combinations-to-fight-complex-diseases-faster/

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November 27, 2023

The Honorable Cathy McMorris Rodgers
Chair, House Committee on Energy & Commerce
2125 Rayburn House Office Building
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The Honorable Frank Pallone
Ranking Member, House Committee on Energy & Commerce
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The Honorable Brett Guthrie
Chair, House Committee on Energy & Commerce Health Subcommittee
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The Honorable Anna Eshoo
Ranking Member, House Committee on Energy & Commerce Health Subcommittee
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Dear Chair Rodgers, Chair Guthrie, Ranking Member Pallone and Ranking Member Eshoo:

Thank you for holding a hearing entitled "Understanding How AI is Changing Health Care" to examine the use of artificial intelligence (AI) in health care. CTA believes the use of AI in health care is an excellent example of how technology can be leveraged to improve lives, while also recognizing the need for consumer protections and safety for high-risk AI applications.

As North America's largest technology trade association, the Consumer Technology Association (CTA®) is the tech sector. Our members are the world's leading innovators – from startups to global brands – helping support more than 18 million American jobs. CTA owns and produces CES® – the most influential tech event in the world. CTA is the trade association representing the more than 1000 companies in the U.S. technology industry. Eighty percent of CTA companies are small businesses and startups; others are among the world's best-known brands. We provide members with policy advocacy, market research, technical education and standards development.

CTA is a leading voice on emerging technology issues, including AI, and their impact on the consumer technology industry. In September, CTA released a *National AI Policy and Regulatory Framework*, consumer research on the level of awareness and interest regarding AI and its applications, and a voluntary consensus-based industry standard that identifies types of bias, sources of bias, and bias management practices for health care applications. As CTA President and CEO, I also recently penned an op-ed in *TechCrunch* entitled "Why Smart AI Regulation is Vital for Innovation and US Leadership" and participated in the Senate AI Insight Forum on Privacy and Liability.

CTA's Health Division strives to increase the use of technology-enabled value-based health care to reduce health care costs and drive better health outcomes. The Division, which is made up of cutting edge small and large companies in the health care and technology sectors, including telehealth and personal health wearable companies, health care payers, health systems and biopharmaceutical innovators, provides policy advocacy, health care market research and standards initiatives that advance the appropriate use of consumer technologies in the health care context.

AI Holds Great Promise in Health Care

The use of AI in health care is not new. The Food & Drug Administration has approved more than 600 AI/ML enabled devices since 1995.[1] Recent developments in generative AI have shown promise in improving drug discovery and development, personalized treatments and provider training.

In a March 2023 letter to the Senate Committee on Health, Education, Labor, and Pensions, CTA highlighted the potential of digital health, including AI, to address health care workforce shortage issues.[2] CTA believes AI is showing promise in reducing provider burden and burnout. Not only are advances in AI revolutionizing the way we detect and treat diseases, but it can also streamline administrative tasks such as scheduling and clinical documentation requirements.[3,4] AI can help health care workers treat patients more efficiently and effectively and address main drivers of burnout.

Leverage Existing Laws & Regulations to Address AI

As outlined in CTA's *National AI Policy and Regulatory Framework,* CTA believes Congress should recognize where existing law can be leveraged to address potential concerns with the uses of AI. For example, CTA believes that in certain instances, existing law already guards against potential bias and discrimination, regardless of whether such harm is human or machine generated. Congress should recognize where such laws provide existing remedies and procedures and avoid duplication of the same. If new lawmaking is necessary, CTA urges legislators to focus on guardrails and outcomes, rather than attempting to rein in specific technologies.

CTA also believes a risk-based approach is the best way to support America's technological competitiveness and culture of innovation while protecting the rights and liberties of individuals. As such, CTA believes governance obligations should apply only on high-risk AI systems making decisions: (1) based solely on automated processing and (2) which have consequential legal or equally significant effect on individuals, or which may impact individuals' health and safety. Decisions that impact an individual's ability to obtain financial services, education, housing, health care, and other essential services such as food and water should also constitute decisions that have critical legal or equally significant effects.

In health care, CTA generally supports FDA's risk-based approach to regulation, including for AI. Non-FDA regulated health care applications that use AI, such as health administrative software or consumer health apps that do not make a medical claim, should be considered low risk. For both scenarios, consensus-based industry standards should play an important role in driving transparency and accountability in AI.

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[1] https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-aiml-enabled-medical-devices

[2] https://cdn.cta.tech/cta/media/media/advocacy/pdfs/cta-help-workforce-letter-fin.pdf?_gl=1*qo1jp3*_ga*MjA1NzY5MDM4My4xNjc4ODkxMDk5*_ga_5P7N8TBME7*MTY5NDg5MTc1MS41NS4xLjE2OTQ4OTMwODUuNTkuMC4w&_ga=2.37671586.38966437.1694811339-2057690383.1678891099

[3] Hazarika, I. (2020). Artificial intelligence: opportunities and implications for the health workforce. *International health*, *12*(4), 241-245.

[4] https://www.fiercehealthcare.com/ai-and-machine-learning/finding-right-candidates-keeping-them-ai-aiding-healthcare-industry-meets

The Role of Industry Standards

Consensus-based industry standards are critical to AI governance and regulatory compliance. CTA is an American National Standards Institute (ANSI) accredited standards development organization. We currently have seven published AI standards, including four on AI in health care: *The Use of Artificial Intelligence in Health Care: Best Practices and Recommendations for Bias Management* (ANSI/CTA-2116); *The Use of Artificial Intelligence in Health Care: Managing, Characterizing, and Safeguarding Data* (ANSI/CTA-2107-A); *The Use of Artificial Intelligence in Health Care: Trustworthiness* (ANSI/CTA-2090); *Definitions/Characteristics of Artificial Intelligence in Health Care* (ANSI/CTA-2089.1).

As previously mentioned, consensus-based industry standards can play an important role for both FDA and non-FDA regulated health care AI-enabled devices and applications. Standards can work in tandem with federal regulations and can be nimbler and more reactive to changes in the market, while underpinned by baseline federal consumer protections and rules. For non-FDA regulated AI-enabled health care devices and applications, which are generally low risk, standards can be important in driving industry best practices and ensuring quality and effective products. In considering federal regulation of AI, we urge Congress to recognize the important role of consensus-based industry standards.

Congress Must Pass a National Privacy Law

To ensure trust and confidence in AI-enabled health care tools, there must be robust data privacy requirements. While the protections provided under the *Health Insurance Portability and Accountability Act* (HIPAA) work well in clinical settings as healthcare providers are covered entities under HIPAA, and therefore they and their business associates must adhere to the law, if patients choose to upload their data to an AI-powered tool of their choosing, that tool would likely not be covered by HIPAA.

CTA advocates for a comprehensive federal data privacy law that preempts state laws. A uniform, technology-neutral, national standard that provides consistent protections across technologies, companies, agencies, and state borders are the bedrock prerequisite to ensure consumer trust, continue data-driven innovation, and safeguard data. A preemptive federal privacy law is the most effective way to achieve such consistency. A federal privacy law should also avoid a private right of action so as not to enable frivolous and harassing lawsuits targeting American innovators and entrepreneurs. Legislation that merely sets one standard and allows states to add additional requirements will confuse consumers and developers, discouraging innovation. A state-centric approach simply does not work in a digital economy, where data flows across borders in a matter of seconds.

Failing to pass federal privacy legislation will cost the American economy more than $1 trillion (about $3100 per person in the United States) over ten years, with more than $200 billion of that being paid by small businesses.[5] As a result, resources that could go toward creating jobs or investing in research will instead be spent on compliance costs and legal bills created by the current state-by-state patchwork of privacy laws. Without Congressional action, we will end up with different laws in all 50 states (there are already 12 states that have enacted comprehensive privacy laws) placing the United States at a competitive disadvantage as other nations enact comprehensive privacy laws.

[5] https://itif.org/publications/2022/01/24/50-state-patchwork-privacy-laws-could-cost-1-trillion-more-single-federal/

Conclusion

Thank you for your leadership to ensure the health care industry and patients everywhere can benefit from the use of cutting-edge technologies such as AI. CTA believes AI holds great promise in addressing some of the biggest challenges facing the US health care system and we look forward to continuing to work with the Committee and Subcommittee to advance the responsible use of AI in health care.

Sincerely,

Gary Shapiro
President and CEO
Consumer Technology Association

Cc:
Members of the Energy & Commerce Health Subcommittee

National Nurses United
The National Voice for Direct-Care RNs

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November 29, 2023

House Energy and Commerce Committee
Subcommittee on Health
2125 Rayburn House Office Building
Washington, D.C. 20515

Dear Chair McMorris Rodgers, Subcommittee Chair Guthrie, and Members of the Committee:

In light of the Subcommittee on Health's hearing today titled "Understanding How AI is Changing Health Care," I write to you on behalf of National Nurses United, the nation's largest union and professional association of registered nurses (RNs) to discuss the ways that our nearly 225,000 members are already experiencing the impacts of artificial intelligence (AI) and data-driven technologies at the hospital bedside.

The decisions to implement AI technologies are often made without the knowledge of either nurses or patients, and are putting patients and the nurses who care for them at risk. AI technology is being used to replace educated registered nurses exercising independent judgment with lower-cost staff following algorithmic instructions. However, patients are unique and health care is made up of non-routine situations that require human touch, care, and input. AI poses significant risks to patient care and to nursing practice, and all legislative and regulatory steps taken must utilize the precautionary principle – an idea at the center of public health analysis – in order to protect patients from harm.

NNU urges the Federal Government to pursue a regulatory framework that safeguards the clinical judgment of nurses and other health care workers from being undermined by AI and other data-driven technologies. NNU recommends that Congress take the following actions:

- **All statutes and regulations must be grounded in the precautionary principle.** NNU urges Congress to develop regulations that require technology developers and health care providers to prove that AI and other data-driven digital technologies are safe, effective, and therapeutic for both a specific patient population and the health care workforce engaging with these technologies before they are deployed in real-world care settings. This goes beyond racial, gender, and age-based bias. As each patient has unique traits, needs, and values, no AI can be sufficiently fine-tuned to predict the appropriate diagnostic, treatment, and prognostic for an individual patient. Liability for any patient harm associated with failures or inaccuracies of automated systems must be placed on both AI developers and health care employers and other end users. Patients must provide informed consent for the use of AI in their treatment, including notification of any clinical decision support software being used.

- **Privacy is paramount in health care -- Congress must prohibit the collection and use of patient data without informed consent, even in so-called deidentified form.** There are often sufficient data points to reidentify so-called de-identified patient information. Currently, health care AI corporations institute gag clauses on users' public discussions of any issues or problems with their products or cloak the workings of their products in claims of proprietary information.

Such gag clauses must be prohibited by law. Additionally, health care AI corporations and the health care employers that use their products regularly claim that clinicians' right to override software recommendations makes them liable for any patient harm while limiting their ability to fully understand and determine how they are used. Thus, clinicians must have the legal right to override AI. For nurses, this means the right to determine nurse staffing and patient care based on our professional judgment.

- Patients' informed consent and the right to clinician override are not sufficient protections, however. **Nurses must have the legal right to bargain over the employer's decision to implement AI and over the deployment and effects of implementation of AI in our workplace.** In addition to statutes and regulations codifying nurses' and patients' rights directly, Congress needs to strengthen workers' rights to organize, collectively bargain, and engage in collective action overall. Health care workers should not be displaced or deskilled as this will inevitably come at the expense of both patients and workers. At the regulatory level, the Centers for Medicare and Medicaid Services must require health care employers to bargain over any implementation of AI with labor unions representing workers as a condition of participation.

- **Congress must protect workers from AI surveillance and data mining.** Congress must prohibit monitoring or data mining of worker-owned devices. Constant surveillance can violate an employee's personal privacy and personal time. It can also allow management to monitor union activity, such as conversations with union representatives or organizing discussions, which chills union activity and the ability of workers to push back against dangerous management practices. The federal government must require that employers make clear the capabilities of this technology and provide an explanation of how it can be used to track and monitor nurses. Additionally, Congress must prohibit the monitoring of worker location, data, or activities during off time in devices used or provided by the employer. Employers should be restricted from collecting biometric data or data related to workers' mental or emotional states. Finally, employers should be prohibited from disciplining an employee based on data gathered through AI surveillance or data mining, and AI developers and employers should also be prohibited from selling worker data to third parties.

These comments are by no means an exhaustive list of concerns, and I am attaching to this letter recent testimony that was given by our Executive Director, Bonnie Castillo, RN, at the Bipartisan AI Insight Forum on the Workforce that was hosted by Senate Majority Leader Schumer.

National Nurses United looks forward to future conversations on this topic, and to working with this committee to ensure that the federal government develops effective regulations that will protect nurses and patients from the harm that can be caused by artificial intelligence and data-driven technologies in health care.

Sincerely,

Amirah Sequeira
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Written Statement for AI Insight Forum: Workforce
Bonnie Castillo, RN, Executive Director, National Nurses United
November 1st, 2023

Thank you, Majority Leader Schumer and Senators Heinrich, Rounds, and Young, for inviting me to participate in this important conversation about the impact of artificial intelligence (AI) on the workforce. My name is Bonnie Castillo, I'm a registered nurse and the Executive Director of National Nurses United, the nation's largest union and professional association of registered nurses, representing nearly 225,000 nurses across the country.

Our members primarily work in acute care hospitals, where they are already experiencing the impacts of artificial intelligence and other data-driven technologies. The decisions to implement these technologies are made without the knowledge of either nurses or patients and are putting patients and the nurses who care for them at risk. AI technology is being used to replace educated registered nurses exercising independent judgment with lower cost staff following algorithmic instructions. However, patients are unique and health care is made up of non-routine situations that require human touch, care, and input. In my comments, I will demonstrate the risks that AI poses to patient care and to nursing practice and propose key legislative and regulatory steps that must be taken to utilize the precautionary principle – an idea at the center of public health analysis – in order to protect patients from harm.

AI and data-driven technologies have already been implemented at acute-care hospitals around the country.

The health care industry has been implementing various forms of artificial intelligence and other data driven technologies for a number of years. The nursing workforce is therefore uniquely situated to provide feedback and analysis on the impacts that these technologies have had on workers and on patients.

Technologies that have already been implemented include the clinical decision support systems embedded in electronic health records (EHRs), acute-care hospital-at-home and remote patient monitoring schemes, virtual acute-care nursing, automated worker surveillance and management (AWSM) and staffing platforms that support gig nursing, and increasingly, emerging technologies like generative AI systems.

Through our experiences working with and around these systems, it is clear to registered nurses that hospital employers have used these technologies in attempts to outsource, devalue, deskill, and automate our work. Doing so increases their profit margins at the expense of patient care and safety.

Many of these technologies are ostensibly designed to improve patient care, but in fact they track the activities of health care workers and are designed to increase billing of patients and insurers. Automated monitoring technology feeds into algorithmic management systems that make unreasonable and inaccurate decisions about patient acuity, staffing, and care with the goal of lowering labor costs. As a result, nurses and other health care professionals are expected to work faster, accept more patients per nurse than is safe, and reduce nurses' use of independent professional skill and judgment. Tracking nurses is designed to facilitate routinization—breaking the holistic process of nursing into discrete tasks—with the goal of replacing educated registered nurses exercising independent judgment with lower-cost staff following algorithmic instructions.

Employers generally assert that these powerful technologies are just updates of older technology that has long been in the workplace, such as treating computer-vision aided cameras the same as traditional security cameras, or EHRs as electronic versions of old paper medical records. However, these technologies are much more than modern iterations of well understood tools and are being introduced widely despite lack of robust research

showing safety, reliability, effectiveness, and equity. Rather, AWSM technologies pull vast and diverse data from an entire ecosystem of monitoring equipment and process this information through opaque algorithms that then make clinical and employment decisions. There is no current method for evaluating AI and no requirement for external validation; it is clear to nurses that AI technologies are being designed to be a replacement for skilled clinicians as opposed to a tool that many clinicians would find helpful.

A "nursing shortage" is often the justification for the deployment of this technology. However, the United States is not experiencing a nursing shortage, only a shortage of nurses willing to risk their licenses and the safety of their patients by working under the unsafe conditions the hospital industry has created. By deliberately refusing to staff our nation's hospital units with enough nurses to safely and optimally care for patients, the hospital industry has driven nurses away from direct patient care. When we add the complete failure by the hospital industry to protect the health and safety of nurses and patients during the Covid pandemic, many nurses have made the difficult decision to stop providing hands-on nursing care to protect themselves, their nursing licenses, their families, and their patients.

Except for a small handful of states, there are sufficient numbers of registered nurses to meet the needs of the country's patients, according to a 2017 U.S. Department of Health and Human Services report on the supply and demand of the nursing workforce from 2014 to 2030.[1] Some states will even have surpluses. The report identifies an inequitable distribution of nurses across the country, rather than a nationwide shortage. In fact, there are 1.2 million RNs with active licenses that are not working as RNs across the United States, and the exodus of RNs from the hospital bedside is ongoing.[2]

AI and data-driven technologies are negatively impacting nursing practice and limiting the use of nurses' professional judgement. This is putting patients and nurses at risk.

Registered nurses have extensive education and clinical experience that enables us to provide safe, effective, and equitable patient care. These standards of nursing care can only be accomplished through continuous in-person assessments of a patient by a qualified licensed registered nurse. Every time an RN interacts with a patient, we perform skilled assessments and evaluations of the patient's overall condition. These assessments are fundamental to ensuring that the patient receives optimal care. Health care is not one-size-fits-all. Nurses must be able to alter expected treatment plans based on the unique circumstances of the patient and the patient's wishes and values and to use their experience and nursing judgment to provide the best course of care. Indeed, we are ethically and legally required to do so. We should not be pressured by management to conform to decisions made by algorithms that are prone to racial and ethnic bias as well as other errors that arise when one applies information that may apply to a population but not to individual patients.

We are already experiencing the degradation and devaluation of our nursing practice through the use of technologies that have been implemented in recent years. For example, health care employers are using EHRs to replace RN judgment by automating the creation of nursing care plans and assigning patient acuity levels. RNs develop the nursing skill and judgment necessary to accurately evaluate a patient and create an effective care plan

[1] Health Resources and Services Administration. 2017. "National and Regional Supply and Demand Projections of the Nursing Workforce: 2014-2030." U.S. Department of Health and Human Services. https://bhw.hrsa.gov/sites/default/files/ bureau-health-workforce/data-research/ nchwa-hrsa-nursing-report.pdf.

[2] NNU has several recent reports on the industry-created staffing crisis and the failure to provide a safe and health work environment. See Protecting Our Front Line: Ending the Shortage of Good Nursing Jobs and the Industry-created Unsafe Staffing Crisis available at: https://www.nationalnursesunited.org/protecting-our-front-line-report; Workplace Violence and Covid-19 in Health Care: How the Hospital Industry Created an Occupational Syndemic available at: https://www.nationalnursesunited.org/sites/default/files/nnu/documents/1121_WPV_HS_Survey_Report_FINAL.pdf; and Deadly Shame: Redressing the Devaluation of Registered Nurse Labor Through Pandemic Equity available at: https://www.nationalnursesunited.org/campaign/deadly-shame-report.

through education and experience in the clinical setting. That human skill and judgment cannot be replaced by an algorithm without serious consequences for safe patient care.

The highly skilled work of a registered nurse, by its very definition, cannot be automated. When hospital employers use technology to override and limit the professional judgement of nurses and other health care workers, patients are put at risk. In fact, patients have already been harmed by AWSM systems, including at least four deaths in the VA health care system linked to errors made by Cerner's electronic health records.[3]

One example that illustrates this risk can be found in efforts to decrease the incidence of sepsis, a complication from infection that carries a high degree of mortality.[4] One AI Early Warning System (EWS) analyzed patient data with the goal of identifying patients with a substantial risk of developing sepsis. The EWS was widely implemented at hundreds of hospitals throughout the country.[5] However, when this sepsis EWS underwent external validation, researchers found that the program missed over 67% of sepsis cases.[6] The authors of this study concluded of the EWS that "it appears to predict sepsis long after the clinician has recognized possible sepsis and acted on that suspicion."

Employers are also using AI to side-step vital RN-to-RN communication during patient hand-off and transfer of duty and to automate patient assignments. Patient transfers are one of the most dangerous points in a patient's care. Disruptions in communication can lead to life-threatening errors and omissions. Our nurses report that AI-generated communication leaves out important information while overburdening nurses with information that is not essential, forcing nurses to waste precious time searching medical records for information that could have been completely and accurately communicated during a brief person-to-person interaction. The use of AI to automate patient transfers has resulted in patients being sent to the wrong level of care because an RN was not involved in comparing the patients' needs with the resources available on the unit. This automation has also resulted in situations where patients were transferred to a room, and the RN did not know that they were there.

This removal of human communication puts both nurses and patients at risk. At one member's hospital in Michigan, the AI system's failure to relay basic information, such as the patient being positive for Covid or the patient having low white blood cell counts, have resulted in nurses needlessly exposing themselves to the virus or immunocompromised patients being placed on Covid or flu units.

We have grave concerns about the fundamental limits on the ability of algorithms to meet the needs of individual patients, especially when those patients are part of racial or ethnic groups that are less well represented in the data. Nurses know that clinical algorithms can interfere with safe, therapeutic health care that meets the needs of each individual patient. While clinical algorithms may purport to be an objective analysis of the scientific evidence, in fact their development involves significant use of judgment by their creators and creates the opportunity for creator bias—from conflicts of interest, limited perspective on the lives of racial minorities, or implicit racial bias—to be introduced into the algorithm.

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[3] Rodriguez, S. (2023, March 21) VA Admits Oracle Cerner EHRM Issues Contributed to 4 Veteran Deaths. EHR Intelligence, Adoption and Implementation News. https://ehrintelligence.com/news/va-admits-oracle-cerner-ehrm-issues-contributed-to-4-veteran-deaths. Accessed October 28, 2023.

[4] Leng, Y., Gao, C., Li, F., Li, E., & Zhang, F. (2022). The Supportive Role of International Government Funds on the Progress of Sepsis Research During the Past Decade (2010-2019): A Narrative Review. *Inquiry : a journal of medical care organization, provision and financing*, *59*, 469580221078513. https://doi.org/10.1177/00469580221078513.

[5] Wong, A., Otles, E., Donnelly, J. P., Krumm, A., McCullough, J., DeTroyer-Cooley, O., Pestrue, J., Phillips, M., Konye, J., Penoza, C., Ghous, M., & Singh, K. (2021). External Validation of a Widely Implemented Proprietary Sepsis Prediction Model in Hospitalized Patients. JAMA Internal Medicine, 181(8), 1065-1070. https://doi.org/10.1001/jamainternmed.2021.2626.

[6] Schertz, A. R., Lenoir, K. M., Bertoni, A. G., Levine, B. J., Mongraw-Chaffin, M., & Thomas, K. W. (2023). Sepsis Prediction Model for Determining Sepsis vs SIRS, qSOFA, and SOFA. JAMA Network Open, 6(8), e2329729-e2329729. https://doi.org/10.1001/jamanetworkopen.2023.29729.

Even under optimal conditions, clinical algorithms are based on population-level data and are not appropriate for every patient. In addition, the way clinical algorithms are implemented, regardless of how they are created, often inappropriately constrains the use of health care professionals' judgment, which can worsen the impact of a biased algorithm. It is essential that the use of race or ethnicity in clinical algorithms is scrutinized, including whether race or ethnicity are serving as proxies for other factors that should be identified explicitly. However, it will not be possible to eliminate the use of judgment or the need for individual assessment in care decisions. These judgments should be made at the bedside between the patient and their health care provider, not by a committee based on population-level data.

The deployment of artificial intelligence should be subjected to the Precautionary Principle test.

Nurses believe that we must approach any change in health care using the precautionary principle; the proposition that, as Harvard University Professor A. Wallace Hayes explains, "When an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause-and-effect relationships are not fully established scientifically."

The deployment of artificial intelligence should be subjected to this precautionary principle test, especially when it comes to patient care. Policymakers must ensure that the burden of proof rests on healthcare employers to demonstrate that these technologies are safe, effective, and equitable under specific conditions and for the specific populations in which they are used, before they are tested on human beings. It is imperative that the usage and process of deployment be as transparent as possible, and that issues of liability are discussed early and often. As nurses, we believe it is unacceptable to sacrifice any human life in the name of technological innovation. Our first duty is to protect our patients from harm, and we vehemently oppose any risk to patient health or safety and quality of care inflicted by unproved, untested technology.

Nothing about artificial intelligence is inevitable. How AI is developed and deployed is the result of human decisions, and the impacts of AI—whether it helps or harms health care workers and the patients we serve—depends on who is making those decisions. To safeguard the rights, safety, and wellbeing of our patients, the healthcare workforce and our society, workers and unions must be involved at every step of the development of data-driven technologies and be empowered through strengthened organizing and bargaining rights to decide whether and how AI is deployed in the workplace.

NNU urges the Federal Government to pursue a regulatory framework that safeguards the clinical judgment of nurses and other health care workers from being undermined by AI and other data-driven technologies. NNU recommends that Congress take the following actions:

1. **All statutes and regulations must be grounded in the precautionary principle.** NNU urges Congress to develop regulations that require technology developers and health care providers to prove that AI and other data-driven digital technologies are safe, effective, and therapeutic for both a specific patient population and the health care workforce engaging with these technologies before they are deployed in real-world care settings. This goes beyond racial, gender, and age-based bias. As each patient has unique traits, needs, and values, no AI can be sufficiently fine-tuned to predict the appropriate diagnostic, treatment, and prognostic for an individual patient. Liability for any patient harm associated with failures or inaccuracies of automated systems must be placed on both AI developers and health care employers and other end users. Patients must provide informed consent for the use of AI in their treatment, including notification of any clinical decision support software being used.

2. **Privacy is paramount in health care -- Congress must prohibit the collection and use of patient data without informed consent, even in so-called deidentified form.** There are often sufficient data

points to reidentify so-called de-identified patient information. Currently, health care AI corporations institute gag clauses on users' public discussions of any issues or problems with their products or cloak the workings of their products in claims of proprietary information. Such gag clauses must be prohibited by law. Additionally, health care AI corporations and the health care employers that use their products regularly claim that clinicians' right to override software recommendations makes them liable for any patient harm while limiting their ability to fully understand and determine how they are used. Thus, clinicians must have the legal right to override AI. For nurses, this means the right to determine nurse staffing and patient care based on our professional judgment.

3. Patients' informed consent and the right to clinician override are not sufficient protections, however. **Nurses must have the legal right to bargain over the employer's decision to implement AI and over the deployment and effects of implementation of AI in our workplace.** In addition to statutes and regulations codifying nurses' and patients' rights directly, Congress needs to strengthen workers' rights to organize, collectively bargain, and engage in collective action overall. Health care workers should not be displaced or deskilled as this will inevitably come at the expense of both patients and workers. At the regulatory level, the Centers for Medicare and Medicaid Services must require health care employers to bargain over any implementation of AI with labor unions representing workers as a condition of participation.

4. **Congress must protect workers from AI surveillance and data mining.** Congress must prohibit monitoring or data mining of worker-owned devices. Constant surveillance can violate an employee's personal privacy and personal time. It can also allow management to monitor union activity, such as conversations with union representatives or organizing discussions, which chills union activity and the ability of workers to push back against dangerous management practices. The federal government must require that employers make clear the capabilities of this technology and provide an explanation of how it can be used to track and monitor nurses. Additionally, Congress must prohibit the monitoring of worker location, data, or activities during off time in devices used or provided by the employer. Employers should be restricted from collecting biometric data or data related to workers' mental or emotional states. Finally, employers should be prohibited from disciplining an employee based on data gathered through AI surveillance or data mining, and AI developers and employers should also be prohibited from selling worker data to third parties.

Thank you again for inviting me to participate in this discussion. These comments are by no means an exhaustive list of concerns. National Nurses United looks forward to future conversations on this topic, and to working with Congress to ensure that the federal government develops effective regulations that will protect nurses and patients from the harm that can be caused by artificial intelligence and data-driven technologies in health care.