**Evidence based Improvement in Public Health Policies**

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COVID-19 pandemic has again shifted the focus on improving public health policies in the United States. However, the improvement in the polices should be based on evidence-based approach during the decision-making process rather than during problem formulation or implementation phases (Lager, 2012). While the decision makers have argued for immediate improvement in the policies for routine and preventive care as well as severe illnesses such as cancer, the decisions have to be based on evidence through scientific research especially focused on vulnerable groups, such as women involved in criminal legal (CL) system, who are found to suffer from high levels of chronic illness, cancer, and infectious diseases (Binswanger et al., 2009; Binswanger et al., 2010; Nowotny et al., 2019) or the patients with stage III of Melanoma skin cancer, more than half of whom have died within ten years after diagnosis (Kirkwood et al. 2001; Nading et al. 2010). Similarly, deeper investigation based on evidence is needed to learn about the factors behind high level of hesitation against the use of COVID-19 vaccines, especially among certain sections of the community (Bhat et al., 2022).

**Literature Review**

Most of the 1.2 million CL-involved women in the United States are on community supervision, with approximately 74% on probation and 9% on parole (Kaebele & Alper, 2020). Although most of these women under CL system are on community supervision, understanding the factors influencing their engagement in regular and preventive health care will help in developing appropriate policies. For the patients suffering from advanced staged melanoma, several new therapeutic options such as dabrafenib and trametinib (combi-treatment) and the checkpoint inhibitor nivolumab have demonstrated improved outcomes (Eggermont et al., 2016; Eggermont et al. 2010). However, understanding the overall costs and those for treating side effects of these two new therapies, will help in evaluating their overall efficacy. In the case of COVID-19 vaccines, there is still considerable hesitation against their use (Bhat et al., 2022). However, it is important to examine the factors responsible for the varied response to these vaccines so that those who have not yet been vaccinated can be encouraged to do so. The literature review included research articles and literature regarding the health service use among community supervision populations, the clinical trials of new therapies for melanoma and their results regarding relapse-free and overall survival of patients and the clinical trials of the three COVID-19 vaccines, namely mRNA vaccines, Pfizer; Modern and Johnson & Johnson. Additionally, factors linked to linked to routine and preventive care, understanding the role of the adverse event profiles of both therapies for melanoma, and side effects of COVID-19 vaccines in terms of their impact on work and life were also reviewed from various sources. The databases that were used to conduct the literature review included ProQuest and EBSCO Host from the Monroe College Library. Search terms were used to obtain relevant literature, such as; criminal legal system, CL-involved women, Medicaid, community supervision, routine and preventive care; advanced staged melanoma, therapeutic treatment for melanoma, relapse-free clinical trial for melanoma therapies, cost of therapy for advanced melanoma, COVID-19 vaccines, clinical trials of COVID-19 vaccines, side effects of COVID-19 vaccines.

Lorvick et al. (2022) conducted the study between January 2018 and April 2020 to examine the factors influencing the use of routine and preventive care among women involved in criminal legal (CL) system, who are sentenced to Probation. Three factors based on Behavioral Model for Vulnerable Populations (BMVP) were examined in the study, namely the sociodemographic and other characteristics of the population, enabling or impeding factors affecting one’s capacity to receive care and health care needs such as morbidities. Data was gathered by interviewing 371 women with Medicaid coverage, who were hired from the probation office of Alameda County, CA. The interviewees responded to various questions about their medical care visits six months prior and to those related to the three factors of BMVP model. The analysis of the data revealed that 82% of the respondents had one chronic illness and 62% two or more chronic illnesses, while 78% were diagnosed with a mental health condition (Loverick et al. 2022). The study also brought out that 62% of women engaged in routine or preventive care during six months prior to the interview. However, in the absence of Primary Care Provider (PCP), only 25-29% received routine or preventive care in any given six-month period. (Loverick et al. 2022). The analysis further revealed that women in the age group of 44-53 and those living with one or more children under age 18 have higher probability of using routine or preventive care. Moreover, having a PCP was strongly related with higher probability of undergoing routine or preventive care, while there is lower engagement following the Affordable Care Act's (ACA) Medicaid expansion. Lastly, higher vulnerability of CL-involved women due to unmet mental health need and severe subsistence difficulty also resulted in lower use of routine or preventive care.

Wahler et al. (2021) conducted a comparative study aimed at assessing the economic impacts of two targeted therapies for patients with skin cancer called cutaneous melanoma, namely dabrafenib and trametinib (combi-treatment), and the checkpoint inhibitor nivolumab, based on the relapse-free and overall survival, and the side effect profiles. The objectives were to analyse the findings with respect to the overall costs and compare the side effect costs of both therapies.

The data on thirty-six categories of adverse events for both the therapies was extracted in 2020 from the original publications of the studies Combi-AD and CheckMate 238. In the former, there were 438 patients in the combi-treatment group and 432 in the placebo group, while in the latter, there were 453 patients in each group. The adverse events were described as grade 1 or 2 events that were assumed to be evenly split and as grade 3 or 4 events with proportions of 80% and 20% respectively. The undefined events were calculated with averaged costs (Wahler et al. 2021).

The study found that by adding the events with no diagnosis reported in the publications, the calculated cost for various adverse events was 861.89 Euros per treatment for combi treatment and 899.28 Euros per treatment for the checkpoint inhibitor (Wahler et al. 2021). For grade 1 and 2 events, the average cost per therapy was calculated at 423 Euros with the combi-treatment and 343 Euros with nivolumab. However, for grade 3 and 4 events, average cost per therapy was calculated at 438 Euros with combi-treatment and 567 Euros with nivolumab (Wahler et al. 2021). The findings revealed that side effects of the treatment is not the decisive factor in the economic analysis of the two therapies and the overall costs of both treatments is very close. Although the number of adverse events with combi-treatment are higher, these are offset by considerable higher costs of some events reported for nivolumab.

Dreyer et al. (2022) conducted the study aimed at explaining and comparing self-reported side effects from Pfizer, Moderna and Johnson & Johnson; the three COVID-19 vaccines that were permitted for use in the U.S. Data was gathered through surveys among the participants of the web-based COVID-19 Active Registry Experience (CARE), who had received all the prescribed doses of these vaccines during March 19 and July 15, 2021. The participants were recruited via social media targeting adult U.S. residents through on-line informed consent. The requested information included the demographic profile, medical history, COVID-19-like symptoms and severity, COVID-19 vaccination, and use of prescription and non-prescription medications and dietary supplements. The vaccinated participants were also asked to provide the date of vaccination, manufacturer, and lot number, if known. Four separate logistic regression model were run for understanding the association of vaccine manufacturer on burden of side effects and self-care.

The study found that the most frequently reported side effects of vaccinations were injection site reactions (78.9%), fatigue (70.3%) followed by headache (49.0%) (Dreyer et al. 2022). Among the three vaccines, recipients of Moderna had a higher percentage of all these side effects. It was also found that one-third of COVID-19 vaccine recipients reported having trouble taking care of themselves due to vaccine side effects after the second dose of Moderna and Pfizer. Younger people in the age group of 18-29 were more than three times as likely to report 3 or more side effects, while African American participants and those who reported having been vaccinated for influenza were less likely to report 3 or more symptoms. The study also revealed that only 3.1% of vaccinate recipients asked for medical care, only 0.3% were hospitalized and 35.4% of employed participants reported working one day less due to post-vaccination side effects (Dreyer et al. 2022). These findings inform on the short-term safety and tolerability of these vaccines.

The three studies (Lorvick et al., 2022; Wahler et al., 2021; Dryer et al., 2022) have helped in identifying evidence-based factors for improving public health policies for regular and preventive health care, severe diseases like melanoma, and COVID-19 vaccines. The study by Lorvick et al., (2022) pointed out that lower use of routine and preventive care is seen among vulnerable CL-involved women with unmet mental health need and severe subsistence difficulty. Therefore, addressing underlying factors, such as daily deprivation and unmet mental health needs and access to insurance and Primary Care Providers (PCPs) will encourage the use of routine and preventive care among CL-involve women (Lorvick et al., 2022). The study by Wahler et al. (2021) found that average cost burden of side effects is low in relation to the overall costs of the two new therapies for melanoma and therefore other factors such as overall survival, relapse-free survival or the disease burden of side effects may determine decisions on treatment. Dreyer et al., (2022) in his study gathered community-based insights that may guide decision making on vaccine options and addressing vaccine hesitancy, including in particular vulnerable populations, such as diabetics and those with autoimmune disorders.

**Discussion**

The news article “DOJ Announces Coordinated Law Enforcement Action to Combat Health Care Fraud Related to COVID-19. Criminal Charges Against Telemedicine Company Executive, Physician, Marketers and Medical Business Owners for COVID-19 Related Fraud Schemes with Losses Exceeding 143 Million US Dollars” by the US Department of Justice (2021), presented health care fraud schemes laundered through shell corporations that exploited the COVID-19 pandemic to make personal wealth at the cost of American tax payers money. The medical professionals, corporate executives, and others took advantage of the national emergency and offered COVID-19 tests to Medicare beneficiaries at senior living facilities, drive-through COVID-19 testing sites, and medical offices, and induced them to provide their personal identifying information and samples to submit claims to Medicare for unrelated, medically unnecessary, and far more expensive laboratory tests. In some cases, the COVID-19 test results were not provided to the patients as well as to their primary care providers in a timely fashion or were not reliable, risking the further spread of the disease, and some of the prescribed tests were even unnecessary. in many cases, the results were not provided to the patients or their actual primary care doctors.  The proceeds of the fraudulent schemes were used to purchase exotic automobiles and luxury real estate (US Department of Justice 2021).

**Fraud Triangle Analysis**

The associated research problem was the fraud caused due to high demand for health care services and inadequate monitoring during COVID-19 pandemic. The example which shows this research problem taking place can be seen in the news article “DOJ Announces Coordinated Law Enforcement Action to Combat Health Care Fraud Related to COVID-19. Criminal Charges Against Telemedicine Company Executive, Physician, Marketers and Medical Business Owners for COVID-19 Related Fraud Schemes with Losses Exceeding 143 Million US Dollars” (US Department of Justice, 2021). A fraud triangle analysis of this research problem showed that pressure, rationalization, and opportunity are present and all three are necessary for the fraud to take place (King Graduate School, 2021).

The first side of fraud triangle analysis is pressure, which means the motivation for committing fraud (King Graduate School, 2021). In the research problem, the existing pressure was the eagerness of the fraudsters to maintain lavish lifestyle through purchase of luxury items such as vehicles, yachts and real estate. Another pressure might be resulting from the socio-economic status of the fraudster, who may come from low income with large family to support and therefore is motivated to make fast bucks to have a lavish lifestyle without working hard. Because of The COVID-19 pandemic, he found a good opportunity to make money because the problem was severe and affected everyone. Due to panic, everyone was willing to pay as much money as required in order to prevent catching the infection.

The second side of fraud triangle is rationalization, which means reasoning for the fraudulent action (King Graduate School, 2021). In this research problem, the unethical rationalization is the belief that if “If I Don’t Do It, Somebody Else Will”, which has been called the futility illusion (Marshall, 2016). Additionally, the unethical rationalization that is most likely to occur within this problem is the belief that nobody is perfect and therefore such frauds can be accepted as part of the mistake one may just do and get away with it (Marshall, 2016). Moreover, since the fraudster belongs to marginalized group and therefore fails to distinguish legitimate criticism from the bias against him and thus do not acknowledge any wrongdoing. Such unethical rationalization has been termed as “The Victim’s Distortion” (Marshall, 2016).

Lastly, the third side of the fraud triangle is opportunity for dishonesty, which is any gap that includes knowledge and power for the fraud to take place (King Graduate School, 2021). In the news article related to the research problem, the opportunity for dishonesty existed due to the temporary waivers of telehealth restrictions enacted during COVID-19 pandemic by offering telehealth providers access to Medicare beneficiaries for whom they could bill consultations. In exchange, these providers agreed to refer beneficiaries to specific laboratories for expensive and medically unnecessary testing (US Department of Justice, 2021). Because of the severity of sickness, fear of death and protocols of covid19, people were willing to spend as much money as needed and this provided good opportunity for fraudsters to exploit the opportunity of telehealth services.

**Conclusion**

To solve the problem linked to this fraud, I will eliminate the opportunity side of the fraud triangle. I chose this side because as health care leaders, we can create conditions where such opportunities for dishonesty by the fraudsters are reduced. This can be achieved through leadership tools such as strategic decision making at the policy level and communication with the beneficiaries (King Graduate School, 2021; n.d., 2022).

Therefore, on one hand the leaders should call for stringent regulations for monitoring the procedures for tele-medication and offer subsidies for the poor and marginalized. On the other hand, there should be larger awareness campaign about possible frauds and scams by the medical staff. Public health institutions should provide communities with the information they have that is needed for decisions on policies or programs and should obtain the community’s consent for their implementation (n.d.). Moreover, they should act in a timely manner on the information they have within the resources and the mandate given to them by the public (n.d.).

**References**

Bhat, A., Browning-McNee, L. A., Ghauri, K., & Winckler, S. (2022). Covid-19 vaccine confidence project. *Journal of the American Pharmacists Association*, *62*(1). https://doi.org/10.1016/j.japh.2021.06.006

Binswanger, I. A., Krueger, P. M., & Steiner, J. F. (2009). *Prevalence of chronic medical conditions among jail and prison inmates in the USA compared with the general population*. Journal of epidemiology and community health. Retrieved July 27, 2022, from https://pubmed.ncbi.nlm.nih.gov/19648129/

Binswanger, I. A., Merrill, J. O., Krueger, P. M., White, M. C., Booth, R. E., & Elmore, J. G. (2010). Gender differences in chronic medical, psychiatric, and substance-dependence disorders among jail inmates. *American Journal of Public Health*, *100*(3), 476–482. https://doi.org/10.2105/ajph.2008.149591

Dreyer, N., Reynolds, M. W., Albert, L., Brinkley, E., Kwon, T., Mack, C., & Toovey, S. (2022). How frequent are acute reactions to COVID-19 vaccination and who is at risk? *Vaccine*, *40*(12), 1904–1912. https://doi.org/10.1016/j.vaccine.2021.12.072

Eggermont, A. M. M., Suciu, S., Rutkowski, P., Kruit, W. H., Punt, C. J., Dummer, R., Salès, F., Keilholz, U., de Schaetzen, G., & Testori, A. (2016). Long term follow up of the EORTC 18952 trial of adjuvant therapy in resected stage IIB–III cutaneous melanoma patients comparing intermediate doses of interferon-alpha-2b (IFN) with observation: Ulceration of primary is key determinant for IFN-sensitivity. *European Journal of Cancer*, *55*, 111–121. https://doi.org/10.1016/j.ejca.2015.11.014

Eggermont, A. M., Suciu, S., Rutkowski, P., Marsden, J., Testori, A., Corrie, P., Aamdal, S., Ascierto, P. A., Patel, P., & Spatz, A. (2010). Randomized phase III trial comparing postoperative adjuvant ganglioside GM2-KLH/QS-21 vaccination versus observation in Stage ii (T3-T4N0M0) melanoma: Final results of study EORTC 18961. *Journal of Clinical Oncology*, *28*(15\_suppl), 8505–8505. https://doi.org/10.1200/jco.2010.28.15\_suppl.8505

*DOJ announces coordinated law enforcement action to combat health care fraud related to covid-19*. The United States Department of Justice. (2021, May 26). Retrieved July 4, 2022, from https://www.justice.gov/opa/pr/doj-announces-coordinated-law-enforcement-action-combat-health-care-fraud-related-covid-19

Kaebele, D., & Alper, M. (2020). Probation and parole in the United States, 2017– 2018. Washington DC: Office of Justice Programs.

Kirkwood, J. M., Ibrahim, J. G., Sosman, J. A., Sondak, V. K., Agarwala, S. S., Ernstoff, M. S., & Rao, U. (2001). High-dose interferon alfa-2b significantly prolongs relapse-free and overall survival compared with the GM2-KLH/QS-21 vaccine in patients with resected stage IIB-III melanoma: Results of intergroup trial E1694/S9512/C509801. *Journal of Clinical Oncology*, *19*(9), 2370–2380. https://doi.org/10.1200/jco.2001.19.9.2370

King Graduate School. (2021). *KG602 Ethics and leadership: an interdisciplinary perspective* [Instructional aid]. King Graduate School, Monroe College.

Lorvick, J., Hemberg, J.L., Browne, E.N. & Comfort, M.L. (2022). Routine and preventive health care use in the community among women sentenced to probation. *Health and Justice 10* (5), 1-10. <https://doi.org/10.1186/s40352-022-00167-9>

Landi, H. (2021, September 20). *Feds charge 138 medical professionals with $1.4B in healthcare fraud, including Telehealth Schemes*. Fierce Healthcare. Retrieved July 4, 2022, from https://www.fiercehealthcare.com/tech/feds-charge-138-medical-professionals-including-doctors-1-4b-telehealth-fraud-case#:~:text=Health%20Tech-,Feds%20charge%20138%20medical%20professionals%20with%20%241.4,healthcare%20fraud%2C%20including%20telehealth%20schemes&text=The%20Department%20of%20Justice%20on,cost%20%241.4%20billion%20in%20losses.

Lager, A. (2012). A pragmatic approach to evidence-based Public Health Policy. *The Open Public Health Journal*, *5*(1), 70–73. https://doi.org/10.2174/1874944501205010070

Marshall, / J. (2016, January 22). *The unethical rationalization list: 24 and counting*. Ethics Alarms. Retrieved July 4, 2022, from https://ethicsalarms.com/2012/04/14/the-unethical-rationalization-list-24-and-counting/

Nading MA, Balch CM, Sober AJ. Implications of the 2009 American Joint Committee on Cancer Melanoma Staging and Classification on dermatologists and their patients. Semin Cutan Med Surg. 2010;29(3):142–147.

Nowotny, K. M., Kuptsevych-Timmer, A., & Oser, C. (2019). Criminal justice contact and health service utilization among women across health care settings: Analyzing the role of arrest. Women's health issues : official publication of the Jacobs Institute of Women's Health., 29(2), 125–134. [https://doi.org/10.1016/j. whi.2018.12.005](https://doi.org/10.1016/j.%20whi.2018.12.005).

*Principles of the ethical practice of public health - NNPHI*. (n.d.). Retrieved July 17, 2022, from https://nnphi.org/wp-content/uploads/2015/08/PHLSposter-95321.pdf

*The 5 most important skills for healthcare leaders: Learning solutions: Talent management system*. Learning solutions | Talent Management System. (n.d.). Retrieved July 18, 2022, from https://www.peoplefluent.com/blog/insights/5-most-important-skills-healthcare-leaders/

Wahler, S., Müller, A., Koll, C., Seyed-Abbaszadeh, P., & Von Der Schulenburg, J. M. (2021). Economic evaluation of adverse events of dabrafenib plus trametinib versus nivolumab in patients with advanced BRAF-mutant cutaneous melanoma for adjuvant therapy in Germany. *Journal of Market Access & Health Policy*, *9*(1). https://doi.org/10.1080/20016689.2020.1861804