Opinion Article

PHYSICIAN GUIDELINE COMPLIANCE: The use of color-coded LDL-C in the patients' chart

Abstract
In the US and most European Countries, the important cause of death is coronary heart disease (CHD). Hypercholesterolemia is the principal risk factor for coronary artery disease. Reduction in coronary events rates in high-risk patients is feasible by altering cardiovascular risk factors. High-density lipoprotein (HDL) and low-density lipoprotein (LDL-C) are significant risk factors for CHD (Assmann, 2006). HMG-Co-A inhibitors are the most effective treatment of cutting LDL-C levels with a subsequent reduction in cardiovascular death and morbidity. A nudge happens when a choice architecture is planned to control behavior predictably without curbing an individual's choice (Patel, 2011). The direction and force should be associated with professional standards for a nudge to be influentialThe essay detailed how patients' and physicians' actions contributed to the increasing incidence of cardiovascular diseases. Performing either a cluster-randomized trial (CRT) or interrupted time series (ITS) design can test the hypothesis that nudges can influence doctors' actions to intensify the use of statins in patients with ASHD. Nudges can be useful in influencing physicians to be proactive and can increase patients' adherence to the therapy. Trust between the patient and his physician is crucial in attaining these goals. Nudges can be a valuable management tool for steering correct behaviors among healthcare providers. The technique is to ensure that physicians see them as something constructive and not irritating or controlling noodges.

Introduction:

The Gap:

In the US and most European Countries, the important cause of death is coronary heart disease (CHD). Hypercholesterolemia is the principal risk factor for coronary artery disease. Reduction in coronary events rates in high-risk patients is feasible by altering cardiovascular risk factors. High-density lipoprotein (HDL) and low-density lipoprotein (LDL-C) are significant risk factors for CHD (Assmann, 2006). HMG-Co-A inhibitors are the most effective treatment of cutting LDL-C levels with a subsequent reduction in cardiovascular death and morbidity.

About 48.6% of American adults over 40 years old are candidates for statin therapy based on the 2013 American Heart Association and the American College of Cardiology guidelines on cholesterol management. The latest directive on cholesterol management recommends statin for these patients. Studies in the US support total cholesterol levels of 150mg/dl and LDL-C levels of 100mg/l promoting "the lower, the better" principle. Randomized clinical trials of the anti-cholesterol drug in high-risk patients showed that reducing LDL-C levels by 1% cut ASCVD risk by 1% (Finkel, 2015). Randomized Clinical Trials involving low to intermediate-risk individuals had shown benefit from HMG-CoA inhibitors therapy. However, both the AHA/ACC and ESC guidelines did not include the cholesterol treatment recommendations for primary prevention for low to medium risk individuals. A gap is evident in the cholesterol treatment guidelines for low-risk individuals (Pavlovic, 2017).

A wider gap is evident in the implementation of these guidelines for high-risk individuals. Several studies have shown that instructions on cholesterol treatment are not executed correctly in clinical practice (Kotseva, 2001; Fernengo, 2000). A study showed only 7.8% in Italy, and

23% in the US of high-risk individuals were able to achieve the LDL-C goals (Straka, 2001). Furthermore, 4E-Registry showed huge discrepancies between guidelines and therapeutic management habits of office-based medical doctors in Germany (Assmann, 2006). From this study, undertreatment was usual with only about 17.3% to 21.3% of high-risk individuals who attained the LDL-C target goal. Overtreatment also regularly happened with 19.4% to 57.3% of low-risk patients were given statins.

Nudging:

A nudge happens when a choice architecture is planned to control behavior predictably without curbing an individual's choice (Patel, 2011). The direction and force should be associated with professional standards for a nudge to be influential. A nudge unit was created by British Prime Minister David Cameron in 2010, using behavioral science to improve government proficiency. The group was able to demonstrate the influence of nudging on peoples' behavior. There was an increase in organ-donor consent rates when messages advocate mutuality and reciprocity. Nudges can be planned to guide, remind, and motivate expected behaviors. Healthcare delivery is improved when focusing on the less-than-optimal performance of the physicians through nudging.

However, persuading physicians to practice functional medicine is difficult to achieve. Fatalistic and top-down schools of thought might explain the intricacies of nudging physicians. The fatalistic school of thought describes arrogant and stubborn physicians are simply unmanageable. To follow this involves accepting an individual physician's preferences. In order to change physicians' behavior, the top-down school of thought, stresses to take away the physicians' freedom of action. Impose clinical algorithms with monetary incentives and penalties are followed (Jackson, 2016). The complexity of medical technology and human biology creates problems with both approaches. Individual patients, diseases, and comorbidities make physicians individualize treatment strategies to achieve optimal medical outcomes. Steering physicians in the right direction through nudging while giving them autonomy to deviate where appropriate is a logical scheme. A randomized clinical trial to reduce antibiotic prescriptions in primary physicians using three behavioral interventions such as alternatives (as pop-ups in the electronic medical records), peer comparison (compare order rates with top-performing peers) and accountable justification (give reason for the deviation) showed significant decline in inappropriate use of antibiotics (Meeker, 2016). The interventions recognized clinical judgment and allowed physicians to use appropriate antibiotics based on clinical findings without penalties.
When electronic health records (EHR) were implemented in the Penn Medicine Nudges Unit to improve health care delivery, generic medicine set as default, prescription of generic drugs increased from 75% to 98%. After myocardial infarction, only 15% are referred to cardiac rehabilitation when it was an opt-in option. Referral increased to 80% after redesigning it as an opt-out option (Patel 2016). Nudging techniques work when properly planned and implemented.

Evidence of the use of nudges in chronic diseases, the National Healthcare Quality Report showed inadequate quality care in patients with chronic diseases despite various interventions. Cancer screenings and adult immunizations increased after computer-generated paper reminders, but unfortunately, this was not successful in chronic diseases like diabetes mellitus and coronary artery disease (Shea, 1996). There was no increase in the use of beta-blockers or cholesterol screening test for coronary artery disease using computer reminders in Veterans Health care system (Demakis, 2000). However, the use of Longitudinal Medical records in community hospitals and outpatient clinics had shown improvement of medical care for both

coronary artery disease and diabetes mellitus. The key to the success of the system was effective design and physicians' acceptance (Sequist, 2005).

The following strategies are implemented to address physician's resistance to nudges: transparency of purpose, co-creation of content, and constructive framing (Navathe, 2019). Explicitly disclosing the default options did not diminish the impact of nudges because transparency provides an avenue for dialogues about the purpose and goals of nudges. Managers and physicians should co-create nudges so that the interventions match with the culture and insights of the organization. Providing feedback on their performances compared to top-notch peers resulted in better health care delivery and patients' outcomes. Nudges that ask clinicians active choice on drug prescription coupled with delivering feedback on how each physicians' performance compared to their peers, increased default prescriptions.

Whom to Blame:

Non-adherence or poor compliance with medications is a global problem of immense magnitude. Non-compliance is a significant concern to physicians because of dangerous treatment outcomes, grave clinical consequences to patients' health, and added economic burden to society by increasing treatment costs. If patients do not obey to the therapeutic strategies, the envisioned favorable effects are not achieved, of even the most sensibly and logically-based treatment plans. Compliance and adherence in healthcare are "patient's behaviors in taking medications, following diet instructions, and execution of lifestyle changes coincide with healthcare providers' recommendation for health and medical advice" (Sackett, 1976). Non-compliance of patients takes different forms like taking prescriptions but not filling it, taking the medicines at the wrong time and dose, adjusting the frequency of doses, not following physicians' instructions, white coat compliance (taking prescription at the time of consult) and drug holidays (patient stopping and restarting therapy).

In a recent report, fifty percent of patients given HMG-CoA inhibitors by primary healthcare physicians fail to achieve cholesterol levels as stipulated in the NICE guideline after two years of intake of statins (BMJ, 2019). The latest findings confirmed the results of other similar studies. Therapeutic compliance involves not only patients' adherence to drugs but also lifestyle changes, diet, and regular exercise. The adherence rate for long term treatment is about 40-50% while short term therapies are 70-80%, and lifestyle changes are 20-30% (Li, 2008). Hypertension therapy adherence is between 50-70%, with only 23% of patients had a compliance rate of about 80%.

Identified causes of non-adherence and non-compliance include patient-related issues, therapy-associated factors, social and economic aspects, disease dynamics, and health care system factors.

Several studies showed that more than 60 years of patients were more compliant in taking their antiepileptic and antidepressant medications (Buck, 1997, Sirey, 2001). Studies involving patients between 40-50 years of age showed higher compliance with increasing age. However, middle age groups (30-59 years) are less compliant, as confirmed by studies in Japan and Singapore. Females follow physicians' advice consistently than their male counterparts. Hispanics, African-Americans, and other minorities had a low compliance rate due to communication problems and low socio-economic status. Patients with low educational status have trust in their physicians' advice thus are more obedient. Oral drugs, shorter duration of treatment, simple instructions, and fewer drug side effects had been shown to improve treatment adherence. Longer waiting time for clinic visits, problems in filling prescriptions,

inaccessible healthcare systems, and discontented patients resulted in defiance to physicians' advice. Patients anticipating worse health status are driven more to conform with therapeutic strategies if they consider the medication to be helpful (Li, 2008).

Healthcare bodies use guidelines and rules to systematize and simplify care to enhance safety, productivity, and efficiency. Healthcare workers, including doctors, have to follow guidelines of hospitals where they are working, government policies, and different health care societies' recommendations. As a result, there are unintended consequences of too many rules. The length, volume, and complexities of guidelines, trivial policy changes, and too many versions of the same rules, create confusion. Healthcare professionals tend to break the rules and may follow the wrong policies. The more rules imposed on workers, the less likely they will comply. Human is logically adaptable and may modify rules which make non-adherence unavoidable.

Solutions:

Simplify and standardize guidelines and policies, avoid information overload, and make guidelines accessible result to improve adherence by the healthcare workers. It is essential for the Healthcare industry to learn from the methods of other high technology industries. In air traffic control, for example, the number of national bodies producing policies is streamlined, performance is systematized, and air traffic controllers participated in creating standard operating procedures. Systems to monitor version control are functional and require air traffic controllers to read and master every single standard operating procedure.

Physicians' treatment strategies should be simplified, expected effects and adverse treatment reactions explained well to the patients and significant others. Patients should develop trust and confidence to the treating physicians to enhance their adherence and compliance to the treatment regimen.

A behavioral experiment on physicians using nudging

Nudges can dramatically enhance patient outcomes and reduce costs by changing physician behaviors and promoting better care. Nudging is about intervening in a subtle way to improve decision making.

The experiment aims to establish the effect of color-coded (RED LDL-C level) paper reminder in the outpatient chart through recording the actions done by the physicians. The response would either be no action or prescribe statins to patients with atherosclerotic heart disease (ASHD). The use of a cluster-randomized trial (CRT) design where individual doctors are randomized as groups in different clinic centers in a locality is a logical plan. CRT focuses on effectiveness by evaluating outcomes under conditions of actual use. The primary outcome is the increased prescriptions and use of statins in patients with ASHD.
LDL-C levels are coded red in the chart during the initial and subsequent consultations. Included in the study are physicians' group in clusters managing patients with ASHD in the different clinics between July 1, 2019, to July 30, 2021. Physician clusters are randomized to either the control group or the experimental group. Comparing baseline data and after 12 weeks follow-up, all patients with ASHD seen and managed by these physicians should have been prescribed with statins.

When individual randomization is not possible and offers considerable time and cost efficiencies, CRT is an excellent choice. However, CRT is typically not blinded, more complex to

design and implement, requires more participants to achieve statistical power and a small number of groups is less likely to control potential biases thus a threat to internal validity.

Another experimental method that can estimate the efficacy of an intervention is to use interrupted time series (ITS) analysis. “A time series is a continuous sequence of observations on a population, taken repeatedly (typically at equal intervals) over time” (Bernal, 2016; Turner, 2019). ITS study, “a time series of a particular outcome of interest is used to establish an underlying trend, which is 'interrupted' by intervention at a known point in time” (Bernal, 2016; Turner, 2019). It is a requirement to differentiate the pre-intervention and post-intervention periods. With this design, a specified intervention period is from July 1, 2019, to July 30, 2021. The alert system (color-coded LDL) is in place starting July 1, 2019, to be done by the clinic nurse or secretary. LDL-C levels are not in red during the pre-intervention period. Data obtained for the evaluation of all responses by physicians (no action vs. prescribing statin) come from logbooks of the different clinics included in the study. The proposed impact model of the intervention is that of a slope change following a lag. At pre-intervention, a line graph is flat then either a sharp rise or a gradual increase in the line graph following the introduction of the nudge. ITS design is not affected by confounding variables like social, economic status, and population age distribution. Time-varying confounders affect ITS results, but with the use of regression models control the confounders. Those with little education can easily follow the results displayed as graphical and numerical illustrations in epidemiological and statistical methods.

In nudging the physicians to increase statin use in ASHD patients, both experimental designs are useful in estimating the efficacy of population-level health interventions. Reliable results are accomplished by controlling the pros and cons of both designs.

Conclusion:

According to the World Health Organization (WHO), 19.9 million people die of cardiovascular diseases, which is 31% of all death worldwide. Cholesterol-lowering agents such as statins are known to reduce the risk of dying from a heart attack and stroke. A 6% fall in heart attacks and strokes follows one mmol reduction in the levels of LDL-C. However, more than 50% of those taking statins in primary care failed to achieve cholesterol goals. Despite guidelines and affordability of statins, people still die of cardiovascular diseases. A closer look at the problem revealed a gap between guideline implementations and how healthcare providers manage their patients. Reasons included information overload with lengthy, complicated, and inaccessible guidelines, trivial or knee jerk policies and too many versions of the same guidelines and policies. Despite adequate education and detailed instructions, the non-compliance of patients compounded the magnitude of the problem. Patient-related factors, features related to therapy, socio-economic dynamics, the healthcare system, and the disease itself contributed to varying compliance rates of the patients. The essay detailed how patients' and physicians' actions contributed to the increasing incidence of cardiovascular diseases. Performing either a cluster-randomized trial (CRT) or interrupted time series (ITS) design can test the hypothesis that nudges can influence doctors' actions to intensify the use of statins in patients with ASHD. Nudges can be useful in influencing physicians to be proactive and can increase patients’ adherence to the therapy. Trust between the patient and his physician is crucial in attaining

these goals. Nudges can be a valuable management tool for steering correct behaviors among healthcare providers. The technique is to ensure that physicians see them as something constructive and not irritating or controlling noodges.

COMPETING INTERESTS DISCLAIMER:

Authors have declared that no competing interests exist. The products used for this research are commonly and predominantly use products in our area of research and country. There is absolutely no conflict of interest between the authors and producers of the products because we do not intend to use these products as an avenue for any litigation but for the advancement of knowledge. Also, the research was not funded by the producing company rather it was funded by personal efforts of the authors.

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