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POLICY ARTICLE

Has the US Centers for Medicare & Medicaid Services' (CMS) ambiguous Fractional Flow Reserve (FFR) reimbursement policy resulted in inequitable and inferior Medicare beneficiary healthcare?

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ABSTRACT

Background: Fractional Flow Reserve (FFR) defines the appropriateness/ inappropriateness of stent revascularization (primary cardiac intervention, PCI), and post-stent FFR verifies revascularization success, which prognosticates immediate and long-term clinical outcomes. CMS, establishing payment for noninvasive FFRCT (FFR computed tomography) for stable patients with intermediate coronary lesions, inherently acknowledges the diagnostic accuracy and superiority to visual (angiographic) assessment, and patient benefit of necessary PCIs while avoiding inappropriate PCIs. While noninvasive FFRCT provides valuable physiological data, its limited availability, 10% incidence of inadequate images preventing FFRCT calculations, low specificity, double exposure to contrast, turnaround time, and upfront costs are problematic; furthermore, FFRCT is not applicable for the 90% of unstable PCI patients. Thus, CMS's ambiguous FFR policy is bizarre by paying for stable patients, and not paying of "unstable" cath lab patients, and in both cases ischemic lesion stratification is beneficial to patients, and the result of FFR non-usage which is detrimental to "unstable" patient management.

Aims and Methods: this communication will provide a perspective, using primarily large trial data publications as to whether the consequences of CMS's ambiguous FFR payment policy adversely and inequitably impacts Medicare beneficiaries.

Results: Among the nearly 1,000,000 PCI patients annually, >200,000 patients undergo inappropriate PCIs, which cause worse clinical outcomes because 20% of patients have uncertain or improper PCI indications, and the flawed angiographic lesions, of which includes ~1/3rd of lesions which are non-ischemic, nevertheless, PCI was performed. Today, 1/4 of PCI patients are >75 years, and PCI is often avoided in many despite being beneficial because these elderly patients have more complex and technically challenging procedures. Furthermore, since 70-85% of PCIs are single vessel angioplasties (SVA), and 1/3rd of lesions have normal FFRs, and require no stenting, this altered interventional strategy would change patient management and insurer reimbursement.

Conclusion: All patients, including Medicare beneficiaries, deserve, and expect their physician's care to be appropriately grounded by an evidenced-based rationale. Interventional cardiologists should not be impeded or encumbered by a CMS non-reimbursement of invasive FFR that inhibits regular FFR utilization while paying for unnecessary PCI procedures and performance of unnecessary surgeries by not paying for an FFR pressure wire, and independent determination of PCI appropriateness. CMS can correct this by requiring that each PCI should be warranted with FFR or another independent metric, and pay only when that is done. Such a policy would immediately improve Medicare beneficiaries' care, provide assurance that whenever or wherever PCI is performed, a Medicare beneficiary can be confident that optimal care is being provided.

Introduction:

Background: Fractional Flow Reserve (FFR) defines the appropriateness/inappropriateness of stent revascularization (primary cardiac intervention, PCI), and post-stent FFR verifies revascularization success, which prognosticates immediate and long-term clinical outcomes. CMS, establishing payment for noninvasive FFRCT (FFR computed tomography) for stable patients with intermediate coronary lesions, inherently acknowledges the FFR diagnostic superiority to visual (angiographic) assessment, and patient benefit of necessary PCIs, while simultaneously avoiding inappropriate PCIs. CMS has established payment (~$2,000) for noninvasive FFRCT's (FFR computed tomography) ability, for stable patients with intermediate coronary lesions, by acknowledging FFR's diagnostic superiority to determine PCI appropriateness. While noninvasive FFRCT provides valuable physiological data, its limited availability, 10% incidence of limited image quality preventing FFRCT calculations, low specificity, double exposure to contrast, increased turnaround time, and upfront costs are problematic. In addition, FFRCT is not applicable for the 90% of "unstable" cath lab PCIs. Thus, CMS's ambiguous FFR policy is bizarre by paying $2,000 for FFRCT in stable patients, and not paying $675 for invasive FFR in "unstable" patients, where in both cases ischemic lesion stratification improves patient outcomes. CMS's non-reimbursement of invasive FFR has encumbered and/or precluded its routine diagnostic use, which has directly caused hundreds of thousands of Medicare beneficiaries to undergo inappropriate, coronary stent procedures, often confounded by aging's anatomical and comorbid complexities, that resulted in unnecessary complications, repeat procedures, worse clinical outcomes, unwarranted deaths, and an avoidable >$1 billion annual expenditure. Coronary artery disease (CAD) patients care requires astute clinical assessment which, when resulting in coronary angiography, should be followed by an independent diagnostic physiologic lesion assessment, ischemic lesion stratification, and only when indicated, PCI, which will result in improved clinical outcomes.

CMS's expectation that a bundled payment to a single healthcare provider, eschewing invasive FFR payment, would continue to motivate providers to utilize non-required invasive FFR, despite having to absorb FFR's cost, decreasing their revenue, was naïve and ingenuous. This policy, producing unnecessary surgeries, has inflicted irreparable harm on the hundreds of thousands of Medicare beneficiaries. CMS has forsaken its mission to attain the "highest level of healthcare for all people, where everyone has a fair and just opportunity to attain their optimal health regardless of race, ethnicity, disability, sexual orientation, gender identity, socioeconomic status, geography, preferred language, or other factors that affect access to care and health outcomes"; this policy has adversely impacted 65 million Medicare beneficiaries, by preventing the independent evidenced-based diagnostic FFR as the PCI arbiter while perpetuating the

antiquated and flawed CA as PCI determinant that now becomes part of the socioeconomic, race, and ethnicity determinants that further produce inequities and differences in access to care, cardiovascular treatment, mortality rate, and causes of readmission. This is crystal clear when reviewing women and non-white patients who have smaller chances of receiving reperfusion therapy, or a PCI strategy, and as a result have worse outcomes. Women and Black patients with acute coronary syndrome (ACS) receive less evidenced-based care than white male patients, and insurance status contributes to this disjunction. While observational outcome studies, after controlling for comorbidities, have shown similar outcomes for Black, Hispanic, Asian, and gender patients, when compared to white patients. Nevertheless, CA remains the method to define anatomy and arterial stenosis severity, with no consistent independent warranting of physiological lesion assessment.[1] Furthermore, since most PCIs are single vessel angioplasties (SVA), diagnostic FFR would significantly alter an interventionist's approach, patient management, and directly change costs: (a) If single or multiple lesions were assessed, and ≥1stents were deployed, a stent patient management program would be instituted; (b) however, since ~70-85% of PCIs are in a single vessel, and 1/3rd of lesions require no PCI, the patient's management changes from stent to medical care, and altered reimbursement, but better results for patients.

PCI-FFR is primarily performed in affluent, large suburban/ tertiary care/university medical teaching centers on younger, stable patients, and only is done on in <8% of Medicare PCI beneficiaries. Since physiologic lesion assessment is not a Medicare PCI insurance payment requirement, FFR pressure wire's cost becomes a financial consideration: the 4x larger PCI bundled payment >$12,000 versus the $2,800 CA payment, and the latter could not easily absorb FFR's ~$675 cost. While wealthy urban/University teaching hospitals have alternative income sources which can absorb FFR pressure wire costs, the impecunious, disadvantaged, struggling inner-city/small community/rural medical centers cannot do this, which forces physicians, absent the availability of invasive FFR, to use the flawed angiogram as the PCI determinant. Financial concerns now influence patient care, and cause inequitable care, perpetuating inappropriate PCI on unsuspecting Medicare beneficiaries and other public insurance alternatives, disproportionately occur within inner city Black and Brown communities, the poor, the LGBTQ, the immigrant, rural communities, farmers, ranchers, and Native Americans. Disadvantaged institutions with small volume labs, and low volume PCI interventionists, do good work, but without FFR categorization and dependency on CA as the PCI determinant have worse outcomes. CMS is an enormous inanimate federal bureaucracy that has no feelings, beliefs, or sympathies, prejudices, biases, racist or discriminatory beliefs, nevertheless, its policies can result in inadvertent inequitable health care delivery. While bureaucrats can manipulate, and write rules and policies that may reflect personal

discriminatory and racial biases, this is not what occurred; while CMS's people work tirelessly for Medicare beneficiaries; a myopic decision never granted approval for vendor applications for invasive FFR reimbursement, and the unintended consequences of that decision has ultimately resulted in substandard care.

Literature Review and Discussion:

Medicare[2] beneficiaries enrolled in capitated Medicare Advantage (MA) programs [private-sector health insurers receive a fixed payment for providing care (in-hospital, skilled nursing, outpatient), and, often, prescription drug coverage], had lower CA and PCI procedure rates than patients enrolled in Medicare Fee for Service (FFS), even though MA[3] paid 5.6% less for hospital services than FFS Medicare and, commercial plans, perhaps, indicating potential harmful restrictive utilization by MA, which seems consistent with the capitated model. If FFR is unavailable, then its cost is non-existent. The financial issues directly affects the aged, the Medicare beneficiaries, whose numbers continue to grow. Hodgson wrote (2012)[4], "For more than 10 years…the importance of routinely performing FFR has been emphasized in review articles and editorials. FFR guidance has been shown to be of value… the procedure is simple and reproducible, and the FFR strategy is highly cost-effective… So, … what part of the FFR link don't interventional cardiologists [or CMS] understand? …the cardiology community should not tolerate continuing to ignore it" and Medicare beneficiaries should know and be assured that FFR validated their PCI appropriateness.

Dr Nanette Wenger (1992)[5] wrote, "'Not only is cardiovascular disease the major cause of death and disability in aged patients, but also the profile of cardiovascular illness in the United States has shifted to encompass predominantly elderly populations. … Yet it is precisely in this population that the traditional exclusion, or at best underrepresentation, of elderly persons in clinical trials has generated an information void." While aging's complexities and comorbidities affect PCI performance, techniques, and outcomes, nevertheless, appropriate PCI, in this active, vibrant, and aging population, is effective, less traumatic, has shorter recovery times, better outcomes, quicker return to functional independence, while avoiding debilitation and dependency, and yet these outcomes could be significantly improved by avoiding unnecessary procedures and associated complications. CT angiography, and FFRCT can reduce the numbers of inappropriate patients undergoing PCI, FFRCT is not applicable to the 90% of "unstable" or incorrectly clinically diagnosed cath lab patients. Invasive FFR, as a requirement to determine PCI appropriateness, would prevent unwarranted PCIs for both wrong clinical indications with non-ischemic lesions, but as well as appropriate clinical indicated patients (e.g., chest pain but non-cardiac in origin) whose coronary lesion was not the cause of patients' clinical syndrome. Finally, post-PCI FFR demonstrates successful revascularization or if abnormal need for FFR optimization with adjunctive procedures.

Clinical indication misdiagnosis is a considerable issue, and in a focused analysis

of 500,154 PCI [CathPCI National Cardiovascular Data Registry (NCDR)] patients[6]: 71% (355,417) had acute indications (e.g., 21% ST-segment elevation myocardial infarction, 21% non-ST-segment elevation myocardial infarction, 29% high-risk unstable angina), with 99% being appropriate; and 29% (144,737) had non-acute indications: with only 50% appropriate, 38% uncertain, and 12% inappropriate. Further studies of 426,880 non-acute PCI patients (NCDR)[7], at 1199 sites, revealed that 51% missed data, and among the other 49%: 50% were appropriate, 36% uncertain, and 12% inappropriate. Demographics of clinical indications of 221,254 non-acute inappropriate PCIs (NCDR)[8] revealed white men with private insurance were more likely to undergo inappropriate procedures than women, non-whites, or Medicare/public insurance patients. Could PCI overuse be related to private insurance? Among the 25% of asymptomatic 306,391 patients within a 1,225,562 elective CA cohort[9]: Hospitals' incidence of asymptomatic undergoing patients CA ranged from 1%-74% patients, and higher rates of asymptomatic CA had lower rates of appropriate PCI, and while lower volume places had higher proportions of appropriate PCIs. What motivated physicians and hospitals to have so many asymptomatic patient CAs, followed by a significant PCI incidence of inappropriate, uncertain, indefinable, or inexplicable reasons?[10] Why do these data sharply contrast with institutions having lower PCI rates, and had higher rates of appropriateness? Insurance reimbursement? These data stimulated physician behavior change. Among 2,685,683 PCIs (NCDR) (2009-2014)[11], a significant decrease in non-acute PCIs (89,704 to 59,375), and inappropriate non-acute PCIs (26.2% to 13.3%) occurred, with minimal use of FFR.

FAME[14,15] meticulously detailed how pressure derived FFR-guided PCI patients benefitted: FFR functionally significant stenoses treated with PCI + optimal medical therapy (OMT) was superior to OMT alone and decreased the need for urgent revascularization[14] and resulted in significantly lower rates of composite endpoints: death, myocardial infarction, or urgent revascularization at 2[16] and 5[17] years, while angiography-guided PCI had worse outcomes. Randomization[18] of intermediate stenoses with FFR $\geq$0.75 to **Defer**-PCI or **Perform**-PCI, (while FFRs <0.75 underwent PCI) at 5-years, had statistically lower composite rates of cardiac death and acute myocardial infarction (AMI) in the **Defer, Perform**, and Reference groups (3.3%, 7.9%, and 15.7%; p<0.05). Outcomes after deferral of PCI were excellent. Multivessel patients[19], in which angiography was the PCI determinant, were randomized to *angiography-alone-PCI, whereas assignees to FFR-guided-PCI were stented if FFR$\leq$0.80.* At 1-year, in the FFR group, the composite endpoint of death, nonfatal myocardial infarction, and repeat revascularizations was significantly reduced (18.3% to 13.2%; p=0,02). What enabled the inappropriate PCIs in the angiographic group was that the visual angiographic lesion assessment was consistently more severe than quantitative measurements as has been shown by

quantitative coronary angiography (QCA)[20], with all PCI treated lesions visually interpreted ≥70% while 25% were <70% by QCA. Thus, a reason for doing inappropriate PCIs, a higher visual estimate of severity. This flaw of visual assessment was evident in outcomes of FFR-guided PCI of 70%-89% stenotic lesions, with 29% having normal FFRs[21]; cohorts with FFR-(> 0.80)-**defe**r PCI, FFR-(≤ 0.80)-**perform** PCI, and a **control** angiography-control-guided group, at 5-years, had statistically different and lower revascularization rates (16% FFR-**defer** vs. 33% FFR-**perform**). FFR lesion stratification resulted into lower in-hospital and follow-up infarctions, major adverse cardiac events (MACE) and improved survival.[22,23,24] FAME[25] analysis of <65 with ≥ 65 years patients, compared Angiographic-PCI with FFR-PCI and degrees of visually estimated stenoses with the proportion of functionally FFR significant lesions; lower in older patients with 50-70%, and 71-90% stenoses had fewer functionally severe lesions, despite a similar significant angiographic appearance. Thus, many older patients with non-ischemic lesions, but angiographically appearing severe lesions had undergone inappropriate revascularization.

Unfortunately, interventionists rarely use FFR despite its importance: 10,496 operators, performed 3,747,866 PCIs (NCDR)[26], with median operator volume of 59 PCIs annually, 44% of operators performed <50 PCIs annually, high volume operators practiced in urban/teaching hospitals, with only 81% having appropriate clinical indications." Operators practicing at low-volume hospitals had higher mortality than those at high-volume hospitals, performed more emergency PCIs for STEMI, used more radiographic contrast, and more fluoroscopy minutes. These were longer procedures on sicker patients, with 19% having inappropriate clinical indications, and no FFR? In a survey, 57% of interventionists[27] used FFR in <1/3rd of cases, 15% never used FFR, reasons given as of no availability (47%), non-payment issues (39%), and, inconvenience regarding exchange guidewires, increased procedural times, reluctance to cross newly deployed stents, and increased contrast and radiation exposure. Paradoxically, despite FFR non-usage, physician evidentiary importance of FFR[28] is observed when management strategy was based on angiography before performing FFR. In ACS and non-ACS patients, reclassification by FFR was high, similar for both groups (38% versus 39%; *P*=NS), but different patterns were observed, with more patients within non-ACS reclassified from revascularization to OMT versus ACS. In ACS, 1-year outcome of patients reclassified based on FFR against angiography was as good as that of non-reclassified patients where FFR (FFR against angiography) was concordant with angiography with no difference in MACE. Moreover, FFR-based deferral to medical treatment was as safe in patients with ACS as in patients with non-ACS; when FFR data were disregarded (6%), worse outcomes occurred: MACE rate (19% vs. 9%), and angina presence (12% vs. 7%). Analogously, FFR assessment of intermediate lesions[29] reclassified 40% of patients from PCI to OMT. And FFR reclassified a determined angiographic PCI

strategy in 30% of vessels, patient management in 27%, and, predictably, 37% of single vessel lesions[30] required no PCI, and were just a coronary angiogram.

If an abnormal FFR is the PCI determinant, would the post-stent angiogram be a satisfactory measure of success?[31,32,33] Apparently, despite satisfactory angiographic appearance, 24%[31] and 21% of post-PCI FFRs remained at ischemic levels (<0.81)[34], and adjunctive post-PCI interventions permitted functional optimization: increasing FFR to >0.86 [0.78 ± 0.08 to 0.87 ± 0.06 ($p < 0.0001$)], and significantly lowered MACE versus when the final FFR ≤0.86 (17% vs. 23%), at 31 ± 16 months. Abnormal post-PCI FFRs[35,36,37,38,39], or FFR refinements such as post-PCI %-FFR-increase[40,41], when adjunctive procedures enabled FFR optimization, outcomes improved. The post-PCI FFR yields significant target lesion revascularization data, germane in determining procedural success, and the need for additional procedures to obtain FFR optimization, which directly relate to patient outcomes and management plans. One in five patients do not have the restoration of normal coronary blood flow until adjunctive procedures are done to normalize the FFR.

Complication rates in elderly PCI patients directly relating to Medicare beneficiaries have made many interventionists hesitant to operate, with 25% of PCI patients, this proportion continuously growing[42], are ≥75 years and now what becomes relevant are the results for octogenarians, who have PCI in-hospital complication rates significantly (2-4x) higher: 7,472 octogenarians[43] compared to 102,236 younger patients (62 years): death (3.8% vs. 1.1%), Q-wave myocardial infarction, stroke, renal failure, and vascular complications. Coronary lesion characteristics[44] make PCI technically more challenging: more ostial, calcified, tortuous, and left main lesions, and increased MACE rates. Analysis of a decade categorized[45] study of 562,640 elderly PCI patients (≥60 years*) with ACS* [STsegment–elevation myocardial infarction (STEMI), non-STEMI, and unstable angina] *or stable non-ACS CAD* (stable angina, old myocardial infarction, and silent ischemia) detailed how both cohorts had significant comorbidities, cardiogenic shock after PCI, bleeding complications, and a higher in-hospital mortality than younger patients, which were directly linked to increasing age, and lower procedural success rates. Nevertheless, regardless of age-decade, successful PCIs were associated with better outcomes, and an immediate survival benefit, despite the comorbidities, including the novel confounder, clinical frailty (i.e., physical functional decline, cognitive impairment, malnourishment, and reduced physical capacity), independently associated with major bleedings, and increased morbidity and mortality. While utilization of PCI in older adults with STEMI and cardiogenic shock has been increasing, it has been paralleled by a substantial reduction in mortality occurred. Frailty was present in 19% of ≥75 years patients (469,390) admitted with AMI, who were less likely to receive PCI than non-frail patients, but when offered PCI, mortality

diminished[46] and 1- and 3-year survival improved[47]. Clinical judgment is critical in assessing older adults, and PCI should not be excluded based on age[48] Appropriate PCI will benefit the elderly despite the higher complication rates, and PCI-treated patients have an improved prognostic profile, which could be further enhanced if inappropriate procedures were avoided.

Financial factors, influence decisions surrounding PCI because regular FFR usage would produce an altered bundled payment revenue structure and a loss in revenue would occur. A significant conversion of potential PCI to CA bundled payments and would create an unsustainable financial headwind for medical centers and cath labs. If considering just the lesions among the 941,248 PCI patients (NCDR)[12] of whom 86% underwent *single vessel (809,473 patients), and 1/3rd* (267,126 patients) were converted from a PCI to a CA procedure the lost revenue ($12,000 PCI to $2,800 CA) would be considerable, ($3.2 billion to now $750mm, and add back the $180mm for invasive FFR pressure wires), a loss for medical centers and a gain for Medicare. Clinical indications remain a problem as is especially with non-ischemic lesions. The work volume of 8936 operators[13], having performed 723,644 PCIs (2009-2014) (42% Medicare), catalogued as low- (<50 PCIs/y) (39%), intermediate- (50-100 PCIs/y) (32%), or high-volume (>100 PCIs/y) (29%) operators, revealed that each group had similar procedural indications [elective (~45%), urgent (~41%), emergency (~15%), and salvage (<0.4%)]; all performed reliable PCI, with low volume operators performing more emergency PCIs. But only 80% of patients had appropriate PCI clinical indications; and 73% of patients were single vessel PCI. Thus, if FFR were regularly performed, a significant number of cases would convert from SVA-PCI to a CA which would dramatically change revenues for all parties and greatly benefits Medicare and all patients. And data shows how finances do come into play with the 2,000 cath labs[49], in 39% of hospitals, quickly established to provide timely PCI for STEMI patients, but the diminishing AMI prevalence (4.0-3.7%) has lowered PCI volumes and revenues, and financial difficulties prevent continuation as a fulltime catheterization laboratory; thus, would medical centers' financial administrators remove the diagnostic FFR pressure wire option as an available physician tools, thereby, negatively precluding FFR's positive affect on patient outcomes while improving their balance sheets? You can imagine hearing a silent conversation's interrogative, "Why use FFR and turn a "profitable" PCI into a potential financial loss coronary angiogram?"

Conclusions:

One-quarter of PCI patients are ≥75 years. All patients, including Medicare beneficiaries, deserve, and expect their physicians to provide appropriately determined care, using an evidenced-based rationale, and do not expect their care to be impeded, shackled, or encumbered by a CMS policy that pays for them to undergo unnecessary and inappropriate surgeries (PCIs), while inconceivable, CMS's failure to pay for an

inexpensive diagnostic FFR pressure wire encourages such a body assault. CMS's policy has permitted the continued use of the flawed angiographic silhouette as the PCI determinant, directly resulting in unsuspecting Medicare beneficiaries, relying upon CMS' mission statement, to have worse clinical outcomes. CMS can correct this by fiat, which would immediately improve Medicare beneficiaries' care, influence private insurers, while providing assurance to the beneficiary that whenever or wherever PCI is performed, he/she can be confident that the indications are warranted, and not hampered by financial considerations. A changed CMS invasive FFR policy would demand that evidence-based FFR-PCI no longer be withheld from Medicare beneficiaries, because for patients: an indicated PCI was warranted and successful; physicians: indicated PCIs improve procedural results, reduce complications, and liability; hospitals: appropriate procedures, unquestioned payments, and risk reduction; private and public insurers: only pay for appropriate PCIs, reduces unnecessary financial outlays, and avoids or mitigates malpractice claims; and medical vendors be compensated for important devices. Finally, an aside, an analogous situation is rapidly approaching, the need for IVUS' interrogation payment to make certain that vessel wall calcification assessment verifies the indication for coronary lithotripsy.

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