Title
Caution in Generalizing Part D Results to Medicare Population—Reply

Journal
JAMA Internal Medicine, 171(4)

ISSN
2168-6106

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Publication Date
2011-02-01

DOI
10.1001/archinternmed.2011.10

Peer reviewed

validated core therapies (sulfonylureas or basal insulin) and less well-validated therapies, including all other noninsulin drugs. The results are reported in the **Figure**. In quantitative absolute terms, sulfonylureas and basal insulins in the well-validated tier obtain the best results, while GLP-1 agonists in the less well-validated tier had the higher proportion of patients at the target level. The proportions of patients attaining the HbA_{1c} target of <7% with other drugs ranged from 19% with α-glucosidase inhibitors to 41% with glinides. All results were characterized by a wide confidence interval.

Comment. Approximately one-half or more of patients with type 2 diabetes did not obtain an HbA_{1c} level lower than 7% in any further step after metformin treatment failure. The descriptive nature of our analysis does not allow a comparative evaluation. However, previous detailed meta-analyses[6] have indicated that all noninsulin antidiabetic drugs have similar effects on HbA_{1c} levels. This also seems consistent with our results, since the wide confidence interval made most drugs fairly similar. It seems unlikely that future studies will improve these percentages substantially, unless therapeutic inertia (the health care provider's failure to increase therapy when the treatment goals are unmet) is bypassed. Most recent RCTs recruited patients with type 2 diabetes with a mean HbA_{1c} level of approximately 8.5%: this may favor a greater absolute HbA_{1c} decrease,[7] but is associated with a lower percentage of patients achieving the ADA HbA_{1c} level target of <7%. A recent retrospective study of 48 000 diabetic patients in the real world suggests that an HbA_{1c} value of 7.5% is associated with the lowest death rate and lowest rate for large vessel disease.[8] One action could be to increase the target in order to have more patients at goal with the best outcomes: our preliminary data indicate that this action would results in approximately two-thirds of patients with type 2 diabetes on intensified insulin regimens achieving the goal of 7.5% for HbA_{1c}, vs approximately 54% (95% CI, 43.5%-64.0%) on the actual target (≤7%). Hopefully, this strategy would not only lead to a cosmetic effect (more patients at goal) but also limit the risk associated with lower targets (<7% or <6.5%). We need more help from those involved in writing guidelines to walk the fine line between searching for a wiser and safer HbA_{1c} goal and minimizing the harms of any treatment.

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Author Contributions: Dr Giugliano had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. *Study concept and design:* Esposito and Giugliano. *Acquisition of data:* Bellastella and Giugliano. *Analysis and interpretation of data:* Giugliano. *Drafting of the manuscript:* Esposito and Giugliano. *Critical revision of the manuscript for important intellectual content:* Bellastella. *Statistical analysis:* Giugliano. *Administrative, technical, and material support:* Esposito and Bellastella. *Study supervision:* Esposito.
Financial Disclosure: None reported.
Online-Only Material: The eReferences are available at http://www.archinternmed.com.

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COMMENTS AND OPINIONS

HEALTH CARE REFORM

Caution in Generalizing Part D Results to Medicare Population

In the August 9/23, 2010, issue, Millett and colleagues[1(p1327)] wrote,

Mean out-of-pocket annual expenditures on all medications decreased by 32% . . . from $1011 to $691, in the year after Medicare Part D was implemented compared with the year before in all Medicare beneficiaries participating in the M[edical] E[xpenditure] P[anel] S[urvey].

This result is 2 to 3 times larger than any result reported among at least 4 previous Part D evaluations (ranging from 13%-18%).[2-5] Millett and colleagues acknowledge the difference but suggest that the prior studies all underestimated the benefits of Part D.

There may be another reason for the anomalous findings. The investigators excluded a large proportion (approximately 60%) of the original 2005 elderly and Medicare-eligible MEPS sample in order to use a longitudinal study design. Such a large exclusion can significantly and systematically diminish the generalizability of the re-

sults to the reference population, in this case Medicare beneficiaries. As a result, other findings in the article by Millet et al[1] are also inconsistent with previous research. For instance, Table 1 of their article[1] suggests that 44% of the Medicare population did not have drug coverage in 2005 and 19% remained without coverage in 2006, when others put those estimate closer to 24% and 10%, respectively.[6] These are not trivial differences, since the magnitude of the effect of Medicare Part D is directly related to levels of drug coverage before and after implementation of the program.

The use of MEPS data and the longitudinal study design make this study a unique contribution to our understanding of the effects of Part D for certain subgroups. However, we urge caution in generalizing these results to the entire Medicare population.

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In reply

Briesacher and colleagues highlight that we identified a greater reduction in mean out-of-pocket expenditures (32%) among Medicare beneficiaries participating in the MEPS[1] than previous studies (range, 13%-18%).[2,3] They suggest that this may be partly owing to the longitudinal study design used, which limits the generalizability of our findings to the elderly Medicare population.

Our study used the Household Component of MEPS, which involves an overlapping panel design in which data are collected in a series of interviews in the same cohort over a 2-year period. This feature means that a longitudinal study design is the most appropriate analytic approach. The alternative approach of comparing 2 cross-sectional samples was not feasible because approximately 50% of MEPS participants in 2005 and 2006 were interviewed in both years, thus precluding the calculation of independent population estimates.

We acknowledge that the proportion of beneficiaries without drug coverage in 2005 and 2006 (prior to and after the introduction of Part D) in our MEPS sample are higher than previously published estimates.[4] Hence, while our estimates of changes in out-of-pocket expenditures for our defined subgroups, such as dual Medicaid and Medicare beneficiaries and those without prior coverage who enrolled in Part D, are robust and consistent with previous studies[5,6] our study may overestimate the net benefit of this program. However, as discussed in our article, estimates from previous studies may be conservative because they sampled beneficiaries receiving their medications from pharmacy chains or enrolled in Medicare Advantage plans. These beneficiaries were more likely to have had drug coverage prior to the introduction of Part D and will have benefited less from this program. For example, only 15% of beneficiaries in a Medicare Advantage plan had no drug coverage prior to the introduction of Part D in the study undertaken by Zhang et al.[3]

Although we found a greater net benefit from Part D than previous studies, our article highlighted the considerable gap between overall reductions out-of-pocket expenditures on medications and the per capita investment in the program ($320 vs $1742 in 2006). This modest financial benefit appears inadequate, given the high public cost of providing pharmacy coverage through Medicare.

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Outcomes of Preoperative Medical Consultation

I would like to thank and congratulate Wijeysundera et al[1] for a superbly performed and important study.[1] I would also like to solicit their thoughts on an additional interpretation of their findings. Perhaps con-