Point Paper for National Centers for Accident Prevention and Control, Board of Scientific Counselors - December 2019 Meeting

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Point papers are a long-standing tradition in military and government policy making circles. Unlike most medical journal papers, they are formatted with a minimum of verbiage to summarize an issue for decision making. The authors write in that tradition, adding references for key points. We speak on behalf of millions of people in pain and their healthcare providers, who have been predictably and unnecessarily harmed by the 2016 CDC Guidelines on prescription of opioids to adults with chronic non-cancer pain.

- Guidelines were not only "misapplied" but factually in error on multiple issues [1]

  o Sweeping conclusions were drawn from very weak data or unsupported opinion. [2].

  o Paucity of long-term trials was incorrectly interpreted as evidence that opioids are ineffective in the long term. [3]

  o Well known genetic factors in opioid metabolism were ignored; these factors invalidate generalization of dose thresholds for effectiveness and risk. [4] [5]

  o Real risk of addiction or mortality from prescription opioids was grossly over-magnified and hyped.

  o Patient addiction from medical exposure is in fact rare. [6]

- Over prescribing of opioid pain relievers by physicians to their patients did not create America's public health crisis -- and data published by CDC prove it beyond contradiction [7]

  o Seniors over age 62 are prescribed opioids for pain four times more often than young adults age 25-34

  o Young adults have overdose mortality six times higher than seniors.

  o Overdose mortality among seniors has been relatively stable for 20 years while skyrocketing in young adults.

  o Prescribing cannot possibly account for this demographic inversion.

- The true cause of the opioid crisis continues to be the illicit use of opioids, particularly heroin mixed with illicit fentanyl. The U.S. Department of Health and Human Services provided further validation of this statement with 2019 data: 47,600 opioid deaths, 14,944 from prescription opioids (scarcely changed from 2012) and 32,656 (68.6%) from illicit opioids.

- Morphine Milligram Equivalent Daily Dose (MMEDD) is not a useful measure in defining limits on opioid dosage and as such, it has been repudiated by the AMA [8]. Its only utility is as a rough guide to the clinician in making a safe transition from one opioid to another.

o Many patients benefit from opioid therapy at dose levels exceeding thresholds proposed in 2016 guidelines -- often for years.

o Individual genetic variations in opioid metabolism render generalizations on dose levels meaningless [op cit, Ref 4, 5]

o AMA House of Delegates Resolution 235 [November 2018] and AMA Board of Governors Study 22 [June 2019] apply directly.

o American Academy of Family Physicians and five other medical associations declared on behalf of front-line physicians [April 2019]: that law enforcement must be removed from doctors' offices. [9]

• Proven-reliable and safe alternatives to opioid therapy for moderate to severe pain do not yet exist.

o Medical evidence for effectiveness of non-pharmacological therapies is very weak; there is no direct comparisons with opioids (a critical absence), and there are no Phase III trials. [10]

o Some published studies comparing NSAIDs to Opioid therapy are fatally flawed by errors of methodology; [11]. Tylenol and Ibuprofen are likewise associated with thousands of hospital admissions for liver toxicity and gastrointestinal bleeds.

o Opioid analgesics must remain an indispensable therapy in pain management for the foreseeable future and this must be acknowledged.

o Incidence of protracted prescribing in opioid-naive post-surgical patients is less than 1%. [12]

o Incidence of diagnoses of post-surgical substance abuse is less than 0.6% -- influenced by hostile regulatory environment as much as by any actual patient drug seeking. [13]

o Mortality risk from managed exposure to medical opioids is on the order of 0.02% per year -- too small to reliably measure or control. [14]. Even for daily dosage greater than 100 MMED, it is only 0.25%/year — comparable to the risk associated with use of anticoagulants to prevent stroke.

- No published trials demonstrate benefit from involuntary tapering of legacy patients. Coerced tapering instead risks patient medical collapse. [15]

o There are no proven profiling instruments with predictive accuracy to assess risks of opioid prescribing in individual patients. [16]

o "Tapering" as now practiced often amounts to unilateral patient discharge and desertion without support.

o There is no medical, ethical, or moral justification for coerced tapering of chronic pain patients who are otherwise stable.

o Denial of effective pain relief to new patients when it is available and managed by medical professionals may be a fundamental violation of human rights.

- If CDC is to rewrite the 2016 CDC guidelines, then AMA House of Delegates Resolution 235 must become an explicit and central guiding principle in recommended practice.

o Guidelines writers' group must include multiple patient advocates and comprehensive pain management experts as voting members.

o Explicit attention must be given to removing 2016 and newer Guidelines from drug enforcement legislation.

o Draft treatment guidelines must be publicly circulated with a 90-day comment period, a commitment to full public transparency and incorporation of the comments received.

References

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Key Messages: “No instrument has been shown to be associated with high accuracy for predicting opioid overdose, addiction, abuse, or misuse “