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The "Mad Protocol Syndrome." 3. A case of statins in primary prevention in elderly people

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Abstract

The "Mad Protocol Syndrome" is a condition in physicians who rigidly or normatively apply clinical guidelines or protocols. This syndrome, understudied but widespread, is seriously dangerous because it generates iatrogenic effects, promotes polypharmacy and drug interactions, is frequently based on controversial, unsound, and rapidly changing foundations due to the rapid emergence of new studies, fails to consider patient-centered care, is not developed collaboratively by medical specialties and patients, is often influenced by powerful interest groups (such as the relationship of almost all panelists on clinical guideline development committees with the pharmaceutical industry), always maintains an exclusively biomedical perspective ignoring broader biopsychosocial viewpoints, and because there are hundreds or thousands (or perhaps millions?) of clinical guidelines that contradict each other in their recommendations. The patient is a biographical, social, and spiritual reality, never an isolated analytical value. No laboratory target (HbA1c, LDL, or blood pressure) justifies destroying a human being's autonomy, lucidity, or daily well-being. "The Mad Protocol Syndrome" ultimately represents the dehumanization of medicine through bureaucracy. To break this absurd cycle of over-prescription and alienation, 21st-century medicine doesn't need to generate more guidelines from distant experts, but rather urgently reclaim the sovereignty of clinical judgment, safe deprescribing tools, and critical methodological approaches that return control to the primary care physician and dignity to the patient. Studying and reflecting on these concepts is the first step toward transforming clinical practice and rescuing the humane, critical, and sensitive medicine that patients so desperately need. Here is an example of clinical guidelines and protocols for statins in primary prevention in elderly people.

Keywords: Guidelines; Methodology; Applicability, Evidence-based medicine; Patient-centered; Personalized medicine, General practice

INTRODUCTION

Clinical practice guidelines provide evidence-based recommendations to optimize patient care, while protocols dictate rigid, step-by-step procedures. In general medicine, these tools are designed to reduce practice variation and translate complex scientific research into actionable, patient-specific encounters (1, 2). However, clinical guidelines face significant systemic challenges. Key problems include a one-size-fits-all approach that fails to account for individual variations, a lack of universal applicability, and potential conflicts of interest. Misuse of guidelines can sometimes lead to suboptimal care (3-5).

The concept we describe as the "Mad Protocol Syndrome" perfectly defines the phenomenn of the tyranny of clinical guidelines or normative biomedical reductionism.

This refers to the growing concern that modern medicine focuses too rigidly on treating isolated biological pathways and rigid, one-size-fits-all algorithms. This severely limits personalized care and ignores the complex, multifaceted realities of human illness (6).

In the scientific and critical medical literature, promoted by movements such as Choosing Wisely, evidence-based medicine without conflicts of interest, and quaternary prevention (7-10), there are blatant examples of guidelines that exhibit these characteristics: medicalization of risk factors, rigid objectives that induce massive polypharmacy in patients with multiple pathologies, a high rate of panelists with conflicts of interest with the pharmaceutical industry, and a complete disconnection from the biopsychosocial model. Below is an example of clinical guidelines and protocols for statins in primary prevention in elderly people.

CLINICAL CASE: The "Mad Protocol Syndrome" applied to the use of statins in primary prevention in elderly patients.

Grace, 79 years old, has the following medical history: mild lumbar osteoarthritis, occasional insomnia. No history of heart attack, stroke, or diabetes (i.e., she is on primary prevention). Social situation: Very active, she walks 5 kilometers daily with her friends and takes care of her grandchildren in the afternoons.

The "Mad Protocol" Approach (The Rigid Approach: "Grace's cholesterol should be that of a 20-year-old")

Grace goes for her routine blood test. The results show a total cholesterol of 260 mg/dL and an LDL cholesterol of 165 mg/dL. The general practitioner, rigidly applying the clinical guidelines of cardiology societies (which systematically lower the "optimal" LDL thresholds based on standardized cardiovascular risk tables), decides that Grace is in "serious danger." He ignores the fact that risk tables (such as SCORE) are primarily validated for younger populations and that, after age 75–80, the association between high cholesterol and all-cause mortality weakens dramatically or even reverses. This phenomenon, often referred to as the "cholesterol paradox" or reverse epidemiology, is a widely documented finding in geriatric medicine. Multiple observational studies confirm that the predictive value of high total or LDL cholesterol weakens significantly after age 70–75, and low cholesterol often becomes a stronger predictor of mortality in this demographic (11–15).

Following the "high-intensity" stepped protocol, he "automatically" prescribes Atorvastatin 40 mg/day. At the three-month follow-up, the LDL has dropped to 110 mg/dL. Although Grace complains of unusual fatigue, the doctor celebrates the success of the "number" on paper and maintains the dosage. Six months into treatment, Grace began to suffer from statin-induced myopathy (intense muscle pain and diffuse weakness in her legs), a very common side effect in the elderly due to the physiological loss of muscle mass (sarcopenia). Due to the pain and weakness, there was a loss of functionality: she stopped taking her daily walks because of the leg pain; a cascade of polypharmacy ensued: to alleviate the muscle pain, she began taking ibuprofen chronically on her own, which caused erosive gastritis with mild upper gastrointestinal bleeding and an increase in her blood pressure; there was a neurocognitive effect: the lack of cholesterol in neuronal membranes, combined with atorvastatin (which is lipophilic), caused memory lapses and confusion, leading her family to fear the onset of Alzheimer's disease.

DISCUSSION

This is one of the most controversial fields in modern medicine. It illustrates how normal aging is medicalized by treating an analytical risk factor (cholesterol) as if it were an imminent disease, ignoring the lack of solid scientific evidence in this age group.

In Grace's case, the doctor suffers from the "Mad Protocol Syndrome": Controversial and weak scientific basis: The large clinical trials that justify the widespread use of statins have historically excluded those over 75 (especially women in primary prevention). Large observational studies show that in healthy elderly individuals, high total cholesterol is associated with greater longevity, as it protects against infections and frailty (16). Massive conflicts of interest: The committees that draft dyslipidemia guidelines are composed almost entirely of professionals with strong financial ties (grants, conferences, consultancies) to the pharmaceutical companies that market statins and the new, expensive lipid-lowering drugs (17). Iatrogenesis due to a purely biomedical vision: By pursuing a surrogate biomarker (LDL), the doctor destroyed Grace's quality of life, transforming a healthy and robust old woman into a frail, polymedicated patient with chronic pain.

What would a Patient-Centered Intervention Plan look like?

If the doctor had practiced sensible, ethical, and evidence-based medicine, he would have done:
1. Risk contextualization: They would have explained to Grace that having cholesterol at 260 mg/dL at age 79 is a common and protective physiological finding, not a disease, provided there is no prior cardiovascular history.
2. Shared decision-making: They would have prioritized maintaining her excellent lifestyle (walking, active social life). They would not have started her on a statin.The result would have been that Grace would continue walking her 5 kilometers daily without pain, without gastric protectors, without anti-inflammatories, and maintaining her mental clarity and independence.

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