

# Forget About Evidence-Based Medicine. The Science No Longer Matters

## Editorial

United Healthcare (UHC), the largest U.S. health insurer [1] recently announced its decision to make Medtronic the preferred, in-network durable medical equipment (DME) provider of insulin pumps. According to the agreement, UHC members with diabetes who meet the company's medical policy criteria will have access only to Medtronic insulin pumps. Members who choose to use another brand of insulin pump will pay out-of-pocket for that "luxury". The company informs us that this decision is part of the its "ongoing efforts to provide a better member experience, while increasing quality and lowering the overall cost of diabetes care in the United States" [2]. This "one size fits all" approach defies current recommendations for personalized diabetes management [3-8] obstructs necessary clinician-patient collaboration [9] and puts patients at risk for increased mortality, hospitalizations and associated costs [10]. In essence, the decision appears to be driven solely by profit motives and is diametrically opposed to recent medical evidence. The purpose of this report is not to disparage in any way the quality of Medtronic insulin pump systems; rather, it is simply to discuss the potential unintended consequences of UHC's decision, regardless of the specific insulin system selected.

## Why Patient Preference Matters

Patient empowerment is a key component of effective diabetes self-management and is associated with increased medication adherence, increased knowledge and desired self-care behaviors [11]. As described by Hernandez-Tejada and colleagues [11] empowerment refers to "the ability to make decisions about the control of one's disease, defined by having both the knowledge required to make informed decisions as well as resources to implement these decisions." Although the UHC decision has some impact on patient knowledge (e.g., limits on patient awareness of all insulin pump options), it significantly restricts patients' financial ability to utilize the insulin pump that meets their specific needs and preferences. Currently available insulin pump systems offer a variety of unique features to accommodate the individual needs of patients [12]. Many of these features, such as display size/readability, wireless remote control, interface with glucose monitoring devices, water resistance and others, can potentially affect insulin pump usability and, ultimately, patient adherence to treatment. Whereas, other features, such as basal increments, bolus delivery options (e.g., square-wave), algorithms used for calculating active insulin can directly impact glycemic control. Moreover, the complexity of the insulin pump can be a major factor in training time and the safe use of these devices. A recent comparison of two insulin pumps by Schaeffer and colleagues [13] found significant in the training time required and, most importantly, user-related errors. In short, one size did not fit all.

## Editorial

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## Protecting Personalized Care

Among the more than 29 million Americans with diabetes, [14] fewer than 53% are achieving their glycemic targets [15]. Helping patients safely achieve desired diabetes control requires utilization of effective tools and therapies that meet the individual needs of each patient. And, because diabetes is predominantly a self-managed disease, patients require strong, empowering patient-physician relationships that support adherence to mutually agreed self-management regimens. **A b o v e** all, patients require choice in the medications and tools they use to manage their disease, which raises important questions that have yet to be answered. Were UHC patients or patient caregivers asked for input regarding this decision? Was input from clinicians or diabetes educators included in the decision-making process? Has any thought been given as to how transitions to the new pumps will be handled? To our knowledge, input from patients/caregivers or healthcare professionals was not sought. In addition to knowledge and motivation, building and sustaining effective patient-clinician collaborations takes time. Unfortunately clinicians are already burdened by the excessive paperwork required to secure reimbursement for their services, and the UHC decision will only increase this burden by forcing clinicians to write (numerous) letters advocating for their patients to receive the most appropriate insulin pump based upon their personal needs.

## Recent History Repeats Itself

Obviously, UHC has failed to grasp the lessons learned from the Medicare competitive bidding fiasco initiated by the Centers for Medicare and Medicaid Services (CMS). As reported by Puckrein and colleagues, [10] the disruption in patient access to blood glucose testing supplies caused by competitive bidding resulted in significant reductions in patient adherence to prescribed testing frequency, which were significantly associated with increased mortality, hospitalizations and costs. Although the

unintended consequences of competitive bidding are, themselves, quite disturbing, even more disturbing is that CMS failed to establish adequate safeguards and mechanisms for monitoring patient safety prior to implementing the program [16]. Has UHC established its own monitoring protocols to identify problems and protect patient safety? Has the company even considered the need for these protocols? We think not. Given the similarities between the competitive bidding program and UHC's recent agreement in restricting access to preferred treatments, we have every reason to believe that UHC members are at similar risk for adverse outcomes seen with competitive bidding.

### Remedies for Protecting Patient Choice

No one should fault Medtronic in its efforts to grow its sales and increase profitability. Without growth and profitability, companies cannot continue to innovate and improve the value and utility of their products. Thus, from a business and legal perspective, voiding the agreement between UHC and Medtronic is not a viable option. However, there are steps that can be taken to minimize the impact of this agreement. **F i r s t**, UHC should immediately develop a protocol that simplifies the process through which clinicians can secure coverage for insulin pumps that are no longer covered. Failure to do so would usurp clinicians' obligation and authority to prescribe the most effective treatments for their patients. Second, patient advocacy groups and medical associations should immediately reach out to other insurers regarding the potential dangers of restricting patient choice. Since the UHC announcement, patient advocacy websites, such as Diabetes Mine and diatribe, have featured comments from patients, voicing their concerns about limiting their access to self-management tools. Likewise, medical associations, such as the American Diabetes Association, American Association of Diabetes Educators and the Juvenile Diabetes Research Foundation, have issued statements advocating for patient choice in their self-management decisions.

Through these efforts, we can, hopefully, prevent the foreseeable "domino effect" of other insurers (government and private) taking similar steps to reduce costs through preferred vendor agreements that further limit access to insulin pumps and, eventually, other technologies (e.g., continuous glucose monitoring).

### Conclusion

Given the increasing prevalence and rising costs of diabetes in America, clinicians and payers must find ways to strike a balance between effectiveness and cost-efficiency in the allocation of healthcare resources. However, UHC's decision to limit patient access to only one brand of insulin pump fails to achieve this balance. Instead, they increased long-term costs that are likely to result from preventable hospitalizations and treatment of complications will far outweigh any short-term savings. Moreover, it is highly unlikely that UHC's anticipated cost savings will be passed on to patients. In essence, patients will be paying the same premiums for less choice and any cost savings will only be reflected in the company's quarterly reports. UHC wins, patients lose. Recent evidence clearly shows that disruption of access to preferred tools and technologies negatively impacts patient adherence to prescribed treatment, resulting in significant adverse

health outcomes. Decisions based on ignorance can be excused if corrected. Corporate greed and shortsightedness cannot.

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