REVIEW



The role of patient education in the prevention and management of type 2 diabetes: an overview

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Abstract The management of type 2 diabetes mellitus includes ability and empowerment of the patient to change lifestyle, maintain an adequate diet and physical activity, manage the disease, and follow a specific program of periodic medical checks and education sessions. In addition, the patient should be able to correctly identify and adequately solve problems related to the disease and actively collaborate with the healthcare system. To obtain these goals, therapeutic patient education (TPE) is now considered a crucial element not only in the treatment but also in the prevention of type 2 diabetes. Several trials showed that TPE is able to improve clinical, lifestyle, and psycho-social outcomes. Nevertheless, studies have not clarified the ideal characteristics of a comprehensive patient education program in clinical practice. Other work is needed to answer open questions regarding the type of PTE (individual or group education), themes, frequency and number of education sessions, contact time between educator and patient, background of educators, use of new technologies, and barriers to self-management. The present review discusses these points on the basis of the most recent data of the literature.

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Therapeutic patient education

According to the World Health Organization Therapeutic Patient Education (TPE) is to train patients in acquiring and maintaining all necessary skills they need to optimally selfmanage their daily living with a chronic disease. In the specific field of diabetes, education has been defined as a systematic intervention involving active patient participation both in self-monitoring and decision making [1]. Diabetes self-management education (DSME) includes all processes that facilitate the knowledge, skill, and ability for diabetes self-care; diabetes self-management support (DSMS) refers to the support that is necessary to implement and sustain coping skills and behaviors needed to self-manage on an ongoing basis [2]. TPE is considered a crucial element both for people with diabetes and those at high risk to develop it, namely in patients with pre-diabetes [3, 4].

Diabetes and pre-diabetes

Diabetes represents an epidemic chronic condition. Among the adults aged 25 years and older, the prevalence of diabetes is greater than 9 % and it will continue to increase [5]; indeed, the number of people with diabetes was 376 million in 2014 and is expected to rise to 591 million by 2030 [6]. Diabetes is a major cause of increased mortality, morbidity, and disability. In diabetic patients the risk of developing cardiovascular diseases (CVD), including coronary artery disease (CAD), stroke, and peripheral

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artery disease (PAD), is increased by two to fourfold and CVD is the main cause of death in diabetes [7–9]. According to recent International Diabetes Federation (IDF) data, diabetes causes 4.9 million deaths per year worldwide, namely every 7 s one person dies from diabetes and about 50 % deaths regard diabetic patients under 60 years of age [6]. In addition, diabetes is a major cause of disability, as it is the leading cause of end-stage renal disease, blindness before 70 years of age, and nontraumatic amputations [9].

Among diabetic patients, about 90 % of them have type 2 diabetes which is characterized by beta-cell dysfunction and insulin resistance and is associated with obesity or overweight [10–12]: these conditions are often due to unhealthy diet and sedentary life [10–13], especially in subjects with genetic predisposition [13].

Pre-diabetes is defined as a condition characterized by glycemia and/or glycated hemoglobin (HbA1c) greater than normal, but not meeting the cut-offs for the diagnosis of diabetes [11, 12]. It represents a strong risk factor for the future development of diabetes and cardiovascular disease [11, 12, 14]. Main pathophysiological bases of pre-diabetes are insulin resistance and beta-cell dysfunction; inadequate diet and sedentary life together with a genetic predisposition and other conditions, such as birth weight [15], play an important role both in the development of pre-diabetes and in its progression to diabetes [10–15].

To find data for this narrative review, searches in MEDLINE, Cochrane Central Register of controlled trials, CINHAL, EMBASE, and SCOPUS were conducted from 1990 to December 2014. Searches were updated in August 2015. The following terms were used in the search: type 2 diabetes, pre-diabetes, patient education, self-management education, prevention, behavioral intervention, lifestyle. English language papers, including randomized controlled trials, meta-analyses, narrative and systematic reviews, guidelines, position statement, recommendations of expert panels, and studies involving at least 50 participants, were taken into account. Then all relevant papers have been evaluated by two independent investigators and both had to agree for the papers to be reported. If there was disagreement, a third reviewer was asked.

General features of the therapeutic patient education

All education actions are based on a specific model which is conceived in order to adequately deal with the complexity of a chronic disease, such as diabetes [16, 17]. In other words, there must be the shift of diabetes care from episodic medical checks toward a chronic care model (CCM). This model adopts a systematic approach to restructuring medical care through partnerships between health systems and communities with a healthcare team that actively collaborates in the patient care [16, 17]. In addition, CCM takes into account all aspects of the patient, including cultural, social, and family features. The main aspects of TPE have been reported in the National Standards for Self-Management Education [3], in the Joint Position Statement of the American Diabetes Association, the American Association of Diabetes Educators, and the Academy of Nutrition and Dietetics [2], and in the International Standards of the IDF [4]. They include ability and empowerment to change lifestyle, maintain adequate diet and physical activity, manage the disease, and follow a program of periodic medical checks and education sessions. The patient should be able also to correctly identify and adequately solve problems due to the disease. The aim of this approach is to obtain an improvement in clinical outcomes, including prevention of complications, global health status, and quality of life. TPE should be an interactive process between health educators and patients. Health educators should enable patients to manage their diabetes autonomously and patients should actively collaborate in this process. To achieve an effective and active PTE, educators should accurately evaluate patients' level of education and knowledge, by setting personalized and compatible goals, and gradually increase their ability to autonomously manage their disease.

There are at least three types of approach to deliver patient education. Education can be administered during usual care, namely during the medical checks. This type of education often represents the simple delivery of information regarding the lifestyle changes and the most important aspects of the management of the disease: information usually is not personalized, but quite standard. In other words, this modality often does not represent a structured education and interaction between patient and team members may be quite scarce. On the contrary, structured TPE has specific characteristics and can be delivered as a group or individual (one-to-one) education. Group TPE may have the following advantages if compared to individual TPE [18, 19]: (1) an increased cost-effectiveness, as it is possible to group together more patients with only one educator; this increases the education time (contact time) to which persons with diabetes are exposed; (2) the possibility for each person to learn from the experiences of other group members. Nevertheless, it may be difficult to implement group education due to logistic and organizational problems [19]. The main advantage of individual TPE is that it really permits to fully personalize intervention and create a mutual trust and strong interaction between patient and educator.

Impact of therapeutic patient education in prevalent and newly diagnosed type 2 diabetes and in pre-diabetes

Several randomized studies assessed the effects of group or individual TPE in type 2 diabetes. A systematic review with meta-analysis that included 11 studies with 1532 people with diabetes showed that group TPE was able to significantly improve HbA1c, glucose levels, systolic blood pressure, weight, and knowledge of the disease [20]. In addition, a reduced need for medication was observed; in particular, it has been found that one out every five patients was able to reduce diabetes medication [20]. Interestingly, the improvement in HbA1c was documented not only in the short-term period (-1.4 % at 4-6 months) but maintained for 2 years (-1.0 %) [20]. The standardized mean difference (SMD) referred that the knowledge of the disease was improved by 1.0 (p = 0.00001) [20]. In the 4-years Rethink Organization to iMprove Education and Outcomes (ROMEO) Italian study, involving 815 noninsulin treated patients in a secondary care clinic setting, group TPE showed improvement in metabolic parameters, quality of life, and knowledge of the disease at the end of follow-up period [21]. In particular, when compared to usual care, at the end of the study cases had higher HDL levels (+0.13 mmol/l) and lower HbA1c (-1.4 %), body mass index (BMI) (-0.4), LDL levels (-0.52 mmol/l), triglycerides (-0.48 mmol/l), systolic (-5.6 mmHg), and diastolic blood pressure (-1.5 mmHg) (p < 0.001 for all)[21]. Interestingly healthy behaviors, quality of life and knowledge of disease were better in cases than in controls (p > 0.001) [21]. In a previous 5-year randomized controlled trial the same researchers showed that a group TPE was able to improve not only all the metabolic parameters but also knowledge of diabetes, problem-solving ability, and quality of life [22] The recent systematic review with meta-analysis by Steinsbekk included 21 studies with 2883 people with type 2 diabetes and showed that a group-based TPE was able to improve metabolic control (as a reduction in HbA1c) at 6 months (-0.44 %), 12 months (-0.4 %), and 2 years (-0.87 %). Interestingly, among lifestyle outcomes, diabetes knowledge was improved at 6, 12, and 24 months (SMD 0.83, 0.85, and 1.59, respectively) and self-management skills at 6 months. Among the psychosocial outcomes, there was a significant improvement in empowerment/self-efficacy at 6 months. No significant information was drawn for quality of life because of the high heterogeneity of the studies [23].

A systematic review with meta-analysis evaluated the effects of individual TPE on metabolic control, diabetes knowledge, and psycho-social outcomes [24]. Nine studies with 1359 patients were included into the analyses. In six

studies comparing individual TPE to usual care, there were no significant differences between the groups in the improvement of metabolic control [weighted mean difference (WMD) in HbA1c: -0.1 %] at 12 and 18 months, even if a significant benefit of individual education on glycemic control was observed in a subgroup analysis of three studies involving participants with a higher mean baseline HbA1c greater than 8 % (WMD: -0.3 %) [24]. In that meta-analysis, no difference in the glycemic control between individual and group TPE was observed (WMD: -0.03 %) [24]. The authors did not provide any information on smoking, dietary self-management, diabetes knowledge, and psycho-social outcomes because of the low number of cases [24]. A recent study involving 623 diabetic adults documented that individual TPE was more effective than group TPE and usual care in reducing HbA1c (-0.51 vs. -0.27 vs. -0.24 %) and that there were no significant differences between group TPE and control group [25]. The percentage of diabetic patients who really achieved the HbA1c target (<7 %) was significantly greater for individual TPE than for group TPE or usual care (21.2 vs. 13.9 vs. 12.8 %). In addition, individual but not group TPE gave some additional benefits in secondary psycho-social and behavioral outcomes, such as physical component score, physical activity, and recommended food score [25]. Compared to group TPE, individual TPE reduced problem area in diabetes and increased self-efficacy [25].

In a large Chinese cohort of 795 type 2 diabetic patients, the Patient Empowerment Programme (PEP) has recently shown that a structured education program (including both group and individual sessions) may not only improve metabolic outcomes and risk factors, but also reduce allcause mortality and cardiovascular diseases [26, 27].

At last, a study suggested that an inpatient diabetes education may be useful in reducing all-causes of re-admission in poorly controlled diabetic patients at 30 and 180 days [28].

A few studies evaluated the impact of TPE in newly diagnosed type 2 diabetic patients. The Diabetes Education and Self-Management for ongoing and newly diagnosed (DESMOND) study showed that in 824 newly diagnosed type 2 diabetic patients a structured group TPE can have beneficial effects on weight (-2.9 vs. 1.8 kg), smoking cessation (odds of not smoking: 3.56), and beliefs about illness at 1 year if compared to usual care [29]. However, this study did not show any difference in HbA1c (-1.49 vs. 1.21), quality of life, and emotional impact of diabetes between intervention and control group at 1 and 3 years [29, 30]. A Canadian study showed that in 803 adults with newly diagnosed diabetes the participation in a introductory diabetes education program was associated with a

significantly adjusted mean reduction in HbA1c between baseline and follow-up of 0.3 % when compared to newly diagnosed patients without such as participation [31]. The authors concluded that this beneficial effect was similar to that observed in subjects with prevalent diabetes. [31].

Another important issue regards the impact that education can have on pre-diabetes. In subjects with pre-diabetes education programs mainly regard interventions on diet and physical activity. The aim is the prevention of diabetes or even the regression of pre-diabetes and diabetes [32, 33]. Lifestyle changes were found to be a powerful tool to prevent the progression from pre-diabetes to type 2 diabetes [15, 34], even if other conditions can play a major role [13, 15]. The large Diabetes Prevention Program study showed that an intensive lifestyle modification can reduce the risk of progression to diabetes by 58 % [35]. A recent meta-analysis confirmed that in people with pre-diabetes, lifestyle interventions may obtain a significantly lower degree of progression toward type 2 diabetes (relative risk: 0.60) with no significant differences between men and women, when compared to usual care [36]. Recently Balk and colleagues showed in a meta-analysis with 53 studies that specific diet and physical activity promotion program was able to reduce incidence of type 2 diabetes by 41 % together with an improvement in body weight and cardiovascular risk profile if compared to usual care [37]. However, the wide variation of programs limited the identification of features most relevant to effectiveness, as observed by the same authors [37]. A Community Preventive Task Force has released some considerations on the need to implement these programs, even if many gaps have been found (evaluation in different populations, effectiveness of programs delivered via internet or other technologies, further comparison between individual and group-based programs) [38].

A recent study showed that a moderate individualized lifestyle intervention provided by nurses and dietitians was able to reduce the incidence of diabetes by 39 % in 269 women at high risk of developing gestational diabetes because of a history of gestational diabetes or a BMI > 30 [39].

Intensive lifestyle intervention can also be effective in determining a partial remission of type 2 diabetes, namely high glucose values below the threshold for the diagnosis of diabetes in the absence of diabetes treatment [40]. However, complete remission (return to a normal glycemia in the absence of a treatment) was rarely achieved [40]. On the other hand, intensive lifestyle intervention can cause not only decrease in body weight and HbA1c but also amelioration of concomitant cardiovascular risk factors, such as blood pressure and lipids [41]. However, so far comprehensive lifestyle interventions failed to show significant reduction in all-cause mortality in type 2 diabetic subjects, microvascular and cardiovascular outcomes [42].

Evidence gaps and open questions in clinical practice

Even if trials globally report positive effects of TPE on clinical, psycho-social and lifestyle outcomes, questions regarding how to deliver education in clinical practice remain.

Themes

An important question regards the themes that a structured TPE should include. As correctly reported in the recent systematic review by Dube [43], the content of the educational interventions of the trials includes basic knowledge of diabetes, diet, exercise, self-monitoring blood glucose, medication taking, reducing risks, problems solving, and living with diabetes. In reality, it is very difficult to perform a long-term trial which includes all the aspects of the patient education and, therefore, each trial can take into account only a limited number of topics. This may imply that results observed in different trials may be variable and not reproducible in the clinical practice. Table 1 depicts the themes potential deliverable during sessions of TPE [1-4, 20-42]. It is evident that all the information cannot be delivered during only one session of TPE. Therefore, a specific education program should be scheduled to address all the issues, even if some topics will be discussed at every meeting while others less frequently. For example, hypoglycemia is an important problem in the management of diabetes not only for quality of life, social, and economic costs [44], but also for the implications in terms of mortality and cardiovascular risk [44, 45]. Nevertheless, some diabetes therapies are not associated with hypoglycemia, while other treatments can cause severe hypoglycemia [46]. This implies that hypoglycemia and its implications have to be explained to all the patients, but frequent reinforcements are needed only in subjects treated with drugs associated with a risk for hypoglycemia.

Neglected themes of education (sexual function, diabetic foot, peripheral artery disease)

Among the potential themes, sexual function should be taken into account, even if it was not explored in trials on TPE. Erectile dysfunction (ED) represents a common complication of diabetes and greatly worsens quality of life [47]. Recent studies have shown that ED is strongly associated with coronary atherosclerosis [48] and that it is a powerful marker of silent myocardial ischemia in diabetes [47, 49]. Considering that men may deny the presence of sexual problems, educators should administer validated questionnaires to detect ED to all the diabetic patients and Table 1 List of potential themes included in a therapeutic patient education for type 2 diabetic patients

- 1. Basic knowledge of diabetes and its complications
- 2. Healthy diet
- 3. Regular physical activity
- 4. Glucose control, modification of diet and treatment before, during and after vigorous physical activity
- 5. Self-monitoring blood glucose
- 6. Prevention and early identification of hypoglycemia
- 7. Prevention and early identification of hyperglycemia
- 8. Management of hypo- or hyperglycemia
- 9. Modification of the treatment on the basis of self-monitoring blood glucose before medical check
- 10. Giving up smoking
- 11. Periodic administration of questionnaires on erectile dysfunction
- 12. Periodic administration of questionnaires on quality of life
- 13. Identification and correct interpretation of some specific symptoms, such as erectile dysfunction, claudication intermittent, unusual dyspnea, paresthesia
- 14. Check blood pressure
- 15. Adherence to medication
- 16. Regular prevention and early identification of diabetic foot
- 17. Regular medical checks
- 18. Regular sessions of patient education
- 19. Management of insulin therapy
- 20. Specific management of gestational diabetes or diabetes during pregnancy
- 21. Management of continuous subcutaneous insulin infusion
- 22. Information on bureaucratic issues, such as guide authorization, voyager, military service, job

should explain them that ED may be a sign of an unknown cardiac disease. In addition, ED may be easily treated and this may improve quality of life [47]. Diabetic foot and peripheral artery disease (PAD) are other common complications of diabetes [50-52], but neglected in the trials on PTE. If they are adequately prevented and early detected it is possible to avoid their dangerous effects, such as amputations, infections, disability, early death, future development of cardiovascular events [49, 53]. On the other hand, specific studies on diabetic foot have shown that TPE, based on the early recognition of lesions and relative conditions of risk, can play a major role both in the prevention and in the early diagnosis of this complication [54, 55]. At last, ED, diabetic foot, and PAD may be used to better stratify the individual cardiovascular risk [47–50, 52, 53].

Number and frequency of sessions

Trials have not definitively clarified number and frequency of education sessions and the ideal global contact time between educator and patient. It is likely that each education session should be repeated every 3/4 months, even if sessions should be closer at the beginning of the educational program. As for the contact time, a meta-analysis documented that each additional hour of contact time is able to reduce HbA1c by 0.04 % [56]. However, future work should clarify this practical aspect.

Professional background of educators

Dube has recently reported that the professional background of the educators vary across the studies with nurses in 8 of 18 as the most common providers, followed by physicians 7 of 18, dietitians/nutritionists 5 of 18, and community support workers or health promoters 2 of 18 [43]. A meta-analysis showed that the effect on HbA1c was not significant, when physicians delivered the intervention (-0.18 %; p = 0.229); conversely with nurses and dieticians, the effect sizes were -0.71 % (p = 0.022) and -0.88 % (p = 0.043), respectively [57]. However, insufficient information on the type of TPE delivered in those studies is available. All members of the healthcare system should be able to provide education at each contact with the patient. This is true for physicians, nurses, dietitians, nutritionists, pharmacists, psychologists, podiatrists, and every health worker. Nevertheless, structured TPE should be delivered by expert and trained educators during specific and periodic sessions. Training for educators should include all the aspects of the education.

New technologies

Use of new technologies may hypothetically play an important role in the education of diabetic patients. A few studies have evaluated the impact on clinical and learning outcomes. A recent systematic review has shown that a computer-based self-management intervention seems to give small beneficial effect on the metabolic control in type 2 diabetic patients [58]. The effect was larger in the mobile phone subgroup, while no beneficial effect was observed in biological, cognitive, behavioral, or emotional outcome [58].

Reinforcement of education

Another issue is represented by the importance of periodic sessions of reinforcement, since the best results obtained with educational intervention are observed at the beginning of the process, but then they generally decline [57]. To avoid drop-out, it could be useful to remind patients about their appointment by phone or text message a few days before the educational session.

Barriers to self-management

As recently reviewed by Ahola and Groop, there are many barriers to self-management of diabetes [59-62]. Some of them are individual (empowerment, literacy, motivation, problem-solving skills, depression, age, cognitive decline, other diseases, and so on) and others are environment related [59]. Educators through an outspoken and confident relationship with patients should identify any barrier. For this purpose, individual sessions may be more useful than group sessions. In addition, individual sessions may be episodically used even when education program is based on group sessions. Important barriers are represented by cultural and language differences of ethnic minorities. For these groups, it is important to use specific tools to adapt education. A recent meta-analysis including 28 studies showed that a culturally adapted education was able to decrease HbA1c over a 24-month period [63]. An improvement in the disease knowledge was observed, but no benefit in other variables, including blood pressure, lipids, and quality of life, was found [63] Improvement in HbA1c, disease knowledge, and quality of life was seen in minorities when tailored interventions were provided [64, 65].

However, the most important problem linked to TPE is that it is often not or only partially delivered. According to some authors, less than 50 % (probably closer to 35-40 %) of all patients with diabetes ever attend a diabetes education/behavioral intervention program and about 50 % complete the program [66]. Costs and organizational problems are often reported as major causes.

Costs

Diabetes has significant economic implications: the costs to society are high and escalating, as about 11 % of worldwide healthcare expenditure, namely US\$ 612 billion, is due to diabetes [6]. Considering that the prevalence of diabetes is increasing, these costs may become prohibitive; this is particularly true if one considers that the constant increase in diabetes incidence is combined with declining mortality, and therefore, there are extensive costs to manage the disease [67]. In addition, a recent study has shown that hyperglycemia greatly increases the costs not only in known diabetic patients, but also in subjects with undiagnosed diabetes or pre-diabetes [68]. TPE seems to be costeffective both in pre-diabetes and diabetic patients [69–71]. Indeed, in pre-diabetes lifestyle interventions are not only effective but also cost-effective, as shown by economic analyses [69]. This has been recently confirmed in the specific meta-analysis with 28 studies [71]. In newly diagnosed type 2 diabetic patients, education was cost-effective and this result was independent of the reduction of HbA1c, as shown by the cost analysis of the DESMOND study that failed to show an effect on the reduction in HbA1c, even if a positive effect on weight and smoking habits was observed [70]. This was observed in other cohorts of diabetic patients even if specific studies should quantify cost-effectiveness of diabetes education [72]. Table 2 summarizes the main findings regarding studies on TPE in diabetes and pre-diabetes [1-4, 20-43, 56, 57, 59, 67-71].

Research needs and conclusions

Studies and meta-analyses showed that TPE is usually associated with an improvement in clinical, knowledge, lifestyle, and psycho-social outcomes, when compared to usual care. Nevertheless many data are needed, in order to definitively answer the questions reported above. In particular, research should clarify the real magnitude of TPE effectiveness and the impact on outcomes in long-term periods. In addition, other longitudinal work should evaluate whether the best results are reached with an individual or a group TPE, even if we should consider the hypothesis that a TPE delivered with both types of sessions may give the best outcomes. At the moment, research in the area of TPE is quite difficult for the reasons reported in the present review and summarized in Table 3. To obtain reliable and comparable data in the future, it may be useful to include in all programs of the trials the main themes suggested by guidelines and position statements; in addition, each trial should add some of the neglected themes. This may permit Table 2Summary of mainfindings from studies ontherapeutic patient education intype 2 diabetes and in pre-diabetes

Approaches to deliver education Nonstructured standard information during medical check Structured group education Structured individual education Structured education with both group and individual sessions Educators Nurses Physicians Dietitians/nutritionists Community support workers or health promoters Location of education Outpatient diabetes clinic Hospital Primary Care Frequency of sessions 3-6 months Number of sessions/year 2_{-4} Main barriers to education Empowerment Literacy Motivation Problem-solving skills Depression Age Cognitive decline Cultural and language differences Improved outcomes observed in studies on therapeutic patients education Metabolic control Blood pressure Lipids Smoking habits Weight Need for medications Knowledge of disease Problem-solving ability Quality of life Physical activity Diet Mortality and morbidity Readmission Prevention of diabetes Regression of diabetes Cost-effectiveness Yes

to standardize the results regarding the main themes and understand if some of the neglected themes may add further benefit. However, the authors should explain in detail all the contents of each theme and specify all aspects, including all tools used to deliver education, such as videos, pictures, technologies. Drop-out may be reduced by using tools to remind the patient about the appointment. All the studies should evaluate not only biomedical but also
 Table 3
 Problems linked to

 research in the area of diabetes
 education

- Specific topics and modalities of education interventions are not described in detail in the studies
 Education themes are not standardized
- 3. Each study uses limited types of interventions and outcomes
- 4. Studies are not comparable for the above reasons and for the different populations evaluated
- 5. It is difficult to do a large trial on long-term period, because of high number of drop-out
- 6. The professional background of educators and the type of their training is often unclear
- 7. There are considerable differences and variations in the content and form of PTE

psycho-social and learning outcomes. In addition, they should obtain more information from all the populations, populations including minorities. Specific studies should evaluate background, role, and training of each potential educator involved in the education program. However, research in the field of TPE is not easy because of its complexity. Indeed, we agree with Jarvis and colleagues: "education interventions will always be complex, as is managing diabetes itself, and evaluating their effectivenesss will always be challenging" [18].

Compliance with ethical standards

The present review complies with ethical requirements. No informed consent was necessary, since no patient was recruited.

Conflict of interest Adriana Coppola, Loredana Sasso, Annamaria Bagnasco, Andrea Giustina, and Carmine Gazzaruso declare that they have no conflict of interest.

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