Interview with a Patients' Advocate

Pia Raanani^a Giora Sharf^b

^aInstitute of Hematology, Davidoff Cancer Center, Beilinson Hospital, Rabin Medical Center, Petah-Tikva, Israel;

^bIsraeli CML Patients Organization, Netanya, Israel

Mr. Giora Sharf

Giora Sharf was diagnosed with chronic myeloid leukemia (CML) in March 2000 at the age of 47. After the initial shock of the diagnosis and some research on treatment options, he chose to wait for a clinical trial with a new agent, STI571. He joined the IRIS trial with Prof. Andreas Hochhaus in June 2000 and after 7 months on interferon treatment, he started taking imatinib. Today, more than 18 years since diagnosis, he is alive and well and has been polymerase chain reaction (PCR) negative for his disease for more than 17 years. As a result, he stopped treatment in 2014 and is monitored very closely by his physician and the PCR results remain at MR4.5–MR5.

Mr. Sharf decided to use his experience to help other CML patients by founding the Israeli CML Patients' Organization in April 2001. What began with 7 local patients in a small hospital cellar in the city of Netanya, Israel, has since grown to support more than 400 patients from all around the country. The main activities of the Patients' Organization are to convey to the patient clear and accurate data on the disease, as well as treatment options, monitoring, and side effect management and to enable patients to be active and involved partners in their own disease management. The organization also provides psy-

chological support to patients who need it. It conducts monthly presentations for patients on various CML-related topics and organizes CML awareness social activities. Many top CML experts in Israel have presented at the Patient Organization events. Additionally, the Organization's Web site, www.cml.org.il, is the first and only site to address CML issues in Hebrew.

In 2014, Mr. Sharf founded a new Israeli Blood Cancer Patients' Organization named "Flute of Light." The Organization is a resource for patients in Israel with leukemia, lymphoma, and other blood disorders. In addition to his work with the Israeli organizations, Mr. Sharf is a co-founder of the CML Advocates Network, which connects 120 leukemia patients' groups from 90 countries from all continents. They organize an annual 3-days' conference for these advocates named CML Horizons, which is focused both on medical updates and advocacy topics. They are also involved in research, and Mr. Sharf has led a global adherence survey for CML patients, which was presented at the European Hematology Association (EHA) 2013 and American Society of Hematology (ASH) 2014 meetings. Recently, Mr. Sharf has led a global patient-based evidence study on treatment free remission (TFR) with more than 1,000 participants from 69 countries.

Mr. Sharf serves on several advisory boards representing the patient's perspective on CML and attends medical

conventions, such as ASH and EHA, to report on updates for patients.

Dr. Pia Raanani

Dr. Pia Raanani, MD is Clinical Full Professor in Hematology at the Sackler School of Medicine, Tel-Aviv University. She has been Head of the Division of Hematology and Hemato-Oncology at the Rabin Medical Center, Petah-Tikva, Israel since 2013.

Her primary field of interest is hemato-oncology, particularly leukemias and lymphomas, and specifically CML. She is the medical advisor of the Israeli CML advocate group. Dr. Raanani trained in hematology at the Sheba Medical Center and completed a fellowship in CML at the Hammersmith Hospital, Royal Postgraduate Medical School in London. In 2007, she established the Hemato-Oncology Hospitalization Unit at the Davidoff Cancer Center, Rabin Medical Center and headed it until 2018. Dr. Raanani is active in the academic life of the Tel-Aviv University: she is a member of several committees, was Head of the Department of Hematology of the Faculty between 2010–2014, and has been Head of the Research Funds Committee of the Sackler School of Medicine since 2014.

Dr. Raanani is on the editorial board of several international hematology journals and a member of the editorial board of the prestigious Cochrane collaboration. She is a member of the Israeli Society of Hematology as well as the European Hematology Association and the American Society of Hematology. Since 2015, she has served as an Ambassador for Israel of the MD Anderson Society of Hematologic Oncology (SOHO). Dr. Raanani has been in the steering committee and has chaired several international scientific meetings in recent years in the field of oncology and hemato-oncology in particular.

Since July 2017 she is Editor-in-Chief of *Acta Haematologica*.

Question 1

Prof. Pia Raanani: As a Patients' Advocate, how do you see the role of Patients' Organizations in 2019 and do you think that they have a potential to influence patients' medical course and healthcare?

Mr. Giora Sharf: I think that this depends a lot on the local health system and it is different from one country to the other. I will relate in my answer to the situation in my country, Israel, but it is also relevant for most of the West-

ern countries in Europe and the United States. I believe that Patients' Organizations are involved in several major areas that can be of help in the fields of patients' medical costs and improvement of healthcare.

The first one is empowerment of the patients. We know from several studies that patients who are empowered by providing them with knowledge of their disease and treatment do better with respect to treatment outcomes, and not less important, they have a better quality of life. So, Patients' Organizations are focused on empowering the patients by giving them the information regarding their disease and treatment.

The second important role of the Patient Advocacy is to advocate for the patients, namely to bring their perspectives where there are unmet needs. For example, in gaining access to treatments as well as in treatment monitoring, especially where patients do not get the best treatment and monitoring at the best timing.

The third role of Patient Advocacy is to advocate for the patients' rights in order to help them to deal with the disease and its outcomes.

And last but not least, is a role in engaging in the research and development of new drugs and in making sure that "patient-friendly" medication and "patient-friendly clinical trials" are developed.

Question 2

Prof. Pia Raanani: Do you think that Patient Advocate groups influence the communication between patients and doctors in 2019?

Mr. Giora Sharf: I think that the answer is yes, and I think that we can as Patient Organizations and Patients' Advocates influence the communication between patients and doctors. I believe that the most important thing is to explain to both physicians and patients that decisions taken today should be shared decisions. In my opinion this is the best model with the best outcome. On the one hand, we see, as part of our role as Patients' Advocates, to explain to the doctors how important it is to share with their patients all the existing treatment options, and on the other hand we see our role in explaining to the patients the challenges that the doctors have in treating them, for example the limited time allocated for each patient. As Patients' Advocates, our role is to bridge between these two "stakeholders," trying to improve their communication. I've been doing the role of Patients' Advocate for 20 years and I feel that we have come through a long way since we started it.

Question 3

Prof. Pia Raanani: Do you think that a model of physician-patient shared decision is good for all patients or should it be personalized, namely right for certain patients and not for others?

Mr. Giora Sharf: Certainly the answer is that we are not dealing with “one size fits all” and that this model should be personalized. The most important thing is to give the patient the option to choose if the model fits his or her own wish. We know that quite a large proportion of patients are not interested in being involved and in taking responsibility for the care of their disease and prefer to leave it in the hands of the physician. We also know that not all patients become members in Patients’ Organizations. Actually, only a minority, between 10–12% of the patients, join Patients’ Organizations. We, as Patients’ Organizations and advocates, should always ask ourselves how we can improve it. I think that a collaboration between Patients’ Organizations and physicians, who are the first point of reference for the patient, is most important and contributing with this respect.

Question 4

Prof. Pia Raanani: How do you see the inter-relationship between patients, doctors, and Pharma? Do Patients’ Advocates and Patients’ Organizations have a role in this relationship?

Mr. Giora Sharf: Doctors, hospital staff, and Pharma companies are talking during the last years about “placing the patient in the center.” But actually, we need to see how this comes into reality in daily life. I believe that all “stakeholders,” including doctors, Pharma companies, and Patients’ Organizations, should be partners since they all have the same goal, namely, to improve the quality of life and the outcome of the patients.

In order to achieve this, we have to be transparent and each of the partners has to be independent and to respect the independence of the other partner.

Question 5

Prof. Pia Raanani: Could you please tell us about the role and involvement of Patients’ Advocates and groups regarding novel agents and the development of the newer drugs?

Mr. Giora Sharf: I think that this is one of the new areas that Patients’ Organizations are getting involved in and it

involves a lot of change, and change is not always easy to accept. Yet, I think that it is beginning to happen and I’m sure that it will continue and evolve further. I and my other colleagues are very much involved today in supporting the development of new drugs for CML. We start by identifying the needs of the patients, thus the process starts even before the development of the drug.

We, as Patients’ Advocates, participate in investigator meetings and in designing patient-friendly protocols and patient-friendly consent forms. As representatives of Patients’ Organizations, we support the recruitment of patients into clinical trials and by participating in investigator committees; we represent the patients’ perspectives and their needs as well as their attitude towards the side effects of treatment.

So, this is how we are involved in collaboration with physicians, scientists, and Pharma companies to make sure that “patient-friendly drugs” are developed.

Question 6

Prof. Pia Raanani: How can Patients’ Organizations be involved in drug approval by the FDA or EMA? How can they help with their reimbursement by the authorities? Can they improve accessibility of patients to the newer drugs on the basis of compassionate use or clinical trials?

Mr. Giora Sharf: Regarding the issue of registration of new drugs and approval by agencies like EMA or FDA: In order to do that, we need to bring the patients’ perspectives into the agencies that are registering the drugs and then to make sure that they are reimbursed by the country or by the local health authorities, especially with the high prices of the newer drugs.

We, as representatives of Patients’ Organizations need to bring up the importance of a drug for the patients and how it actually influences patients’ lives, especially their quality of life.

Actually, today the FDA and the EMA do not register or approve new drugs without the active involvement of patients’ representatives. There are cases when patients need drugs that have not yet been approved but there are indications that the drugs might be helpful. In these cases, we as Patients’ Advocates collaborate with the physicians in their efforts to convince the Pharma companies to initiate compassionate use programs and make the drugs available for the patients.

This collaboration and efforts to launch compassionate use programs are especially important in countries like in Eastern Europe, where not all drugs are available.

Question 7

Prof. Pia Raanani: Can you tell us whether there's a difference between patients included in supportive groups or in Patients' Organizations with respect to issues such as adherence to treatment?

Mr. Giora Sharf: It is interesting that although CML patients have to take their drugs in order to survive, about 30% of them are not taking it properly. Therefore, our Israeli Patients' Organization together with your department, Prof. Raanani, collaborated on a study focusing on CML patients, examining the influence of an intervention to improve adherence of patients to treatment. One of the findings of the study was that patients who were members of the Patients' Organization in Israel were more adherent to the treatment. This is just an example of how Patients' Organizations can educate patients about different issues, such as adherence.

Question 8

Prof. Pia Raanani: As the cofounder of the CML advocate network, which connects 121 Patients' Organizations from 91 countries, do you see a difference in the role of these organizations between different countries?

Mr. Giora Sharf: The answer is absolutely yes. Some of the organizations represent Western developed countries with very good access to treatments and to treatment monitoring, while some of them represent countries from Africa, Asia, and South America, where the patients do not have full access neither to treatment nor to treatment monitoring. Thus, Patients' Organizations in different countries have different roles.

Question 9

Prof. Pia Raanani: What is the role and involvement of family members and caregivers in patient supportive groups?

Mr. Giora Sharf: I think that this is something that was not handled in the right way in the past. When I established the CML Patients' Organization in Israel about 19 years ago, we focused on the patients only. We then got feedbacks from the family members and the caregivers of the patients that the illness is actually influencing their lives no less than that of the patient. Yet, actually nobody relates to the challenges that the caregivers are facing.

So now I think that we understand it better. We therefore initiated a new program of mentoring, where we educate and teach patients and caregivers who have already dealt with the disease to help and support newly diagnosed patients as well as their caregivers. So, today we understand better how to support and help the caregivers as well as the patients.

Question 10

Prof. Pia Raanani: And finally, Giora, how do you see the future with respect to the existence and involvement of patient advocacy or supportive groups?

Mr. Giora Sharf: I think that the need will always be there. There's no question in my opinion that we will always need Patients' Organizations to help and support patients and their caregivers. But I think that Patients' Advocates will need to be more professional. This is not easy. There are many challenges: you have to be fully dedicated about what you do because you have to devote a lot of your time for this. In most cases, it is completely a voluntary work. We have to find a way how to professionalize Patients' Organizations. Also, Patients' Advocates should undergo professional training. I can just mention one example, which is called EUPATI, the European Patient Academy for Innovative Medicine, where patient advocates train for 1.5 years.

I believe that we have to educate our Patients' Advocates everywhere to provide professional services and qualified support for the patients. All this will continue into the future for sure!