

Patient associations as stakeholders: a valuable partner for facilitating access to therapy

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One set of important objectives of patient associations is to provide education, support, and advice to those affected by cardiac arrhythmias to ensure that they have access to appropriate diagnosis and treatment. In this perspective it is essential to establish a balanced partnership between patients and clinicians in order to facilitate the work of the patient association. Such associations must work under the guidance of and in consultation with a medical advisory committee for the production of appropriate and validated educational and awareness materials. Patient association coalitions represent and promote partnerships between professionals, patients, government, organizations, and industry. The power of an alliance works in bringing pressure to bear, in lobbying on behalf of specific patient groups. This type of coalition may also act as a depository for relevant databases and contact information relating to all the members who participate in the coalition, and facilitate rapid and complete communication between all interested parties. When fully developed it may also serve to provide current information on the diagnosis, treatment, and management of cardiac arrhythmias to patients, paramedical staff, and physicians. The Arrhythmia Alliance, initially established in the UK but now developing on an international basis sources, collates, and reflects views and data collected from members, bringing beneficial perspectives to the fore to ensure that change is led by the people and for the people.

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Patient organizations play a vital role in national health systems, forging a pathway for both patients and clinicians to access new and innovative treatments, as well as providing government departments with the necessary research and background information to enable them to make informed decisions. These organizations provide information, advocacy, and support to millions of people each day. The Arrhythmia Alliance (A-A) is one such patient group set up specifically to provide information, support, and access to established or innovative treatments for cardiac arrhythmias. The organization's work in campaigning on behalf of patients with arrhythmias has seen great advances in not only raising awareness of heart rhythm disorders, but in ensuring that patients have access to appropriate diagnosis and treatment. However, patient associations also play a crucial role in educating the public about specific conditions, and with wider internet access, these organizations are now often the first port-of-call for people when either a patient, or a family member, has been diagnosed with disease. Like many patient associations, the A-A works closely with medical professionals, government organizations, health-care providers, patients, carers, and other patient groups to support those with arrhythmias. This collaboration provides the public with much needed access to information and signposting to appropriate services and treatment options, but there is still more that needs to

be done in this area to ensure that patients are provided with the best care options possible.

The role of joint working between specialist clinicians and patients within patient associations should not be underestimated. At a time when national governments are implementing austerity measures and cutting back on healthcare and its budgetary support, patient groups, along with specialist clinicians, can continue to work together in partnership to ensure that key messages are heard by policy makers and filtered down to all levels of the health system. Joint working can also help patient associations form clear messages and calls for action, highlighting issues that may not necessarily have been considered by decision makers. In addition to this, care alliances are able to put pressure on governments to consider those issues outside of the economic sphere. For instance, patient groups will often focus on the quality and value of life, as well as highlighting the importance of improved quality of care, both of which are necessary, yet can be overlooked when forming national policy. Patient organizations do play their part in the process, providing evidence for innovative projects, and treatments that not only reduce mortality and morbidity, but also deliver innovative and cost efficiency savings. This work can be key in shaping policy, providing decision makers with the research and evidence that they require. Patients associations

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also collect data and case stories from patient advocates, providing an 'information library' on the diagnosis, treatment, and management of patients. By collating this information, they are then able to produce up-to-date materials for patients to give to their medical professional, or that health professionals themselves can use for developing services.

Patient care organizations, by keeping accurate records of the patients who seek their help can build, with the cooperation of their patient members, a large database that can be used to rapidly conduct surveys on behalf of health-care payers or providers, industry, or government. Similarly, electronic access allows the testing of various methods of educating patients about aspects of their healthcare and keeping them up to date with developments in the medical arena that may affect them and their care.

Partnership working coordinated by patient groups therefore plays an incredibly important role in helping to shape the national health agenda. This unique specialist knowledge, along with data and case stories, helps to deliver clear messages to government. 'Patient power' is one of the most effective ways in which these groups are able to exert their influence on policy makers. However, with the Government, or other health-care payers, looking at a number of health conditions at any one time, and with the number of patient associations rising, it can be difficult for organizations to get their messages across to the relevant decision makers. It is therefore sometimes necessary for several patient organizations to join together to campaign on a particular issue, utilizing each organizations' membership and key strengths in order to raise widespread awareness of a particular issue. The methods used in patient lobbying have increased in recent years, and with a number of media resources now able to carry key messages on a national and local scale, patient organizations are no longer restricted to a set menu of activities, but can incorporate a number of original ideas in order to raise awareness of a condition. However, as governments and priorities change, organizations must continue to evaluate and develop means of delivering their messages to ensure that conditions are adequately acknowledged and addressed. Arrhythmia Alliance, along with its sister charity, Atrial Fibrillation Association (AFA) recently undertook a national lobbying campaign to give patients access to a new and innovative treatment, a campaign that was not only successful in persuading the government to review its original decision, but also showed how patient associations can incorporate a number of methods to put pressure on decision makers.

In 2008, a new anti-arrhythmic drug was submitted to the National Institute for Health and Clinical Excellence (NICE) for approval. This represented the first new anti-arrhythmic drug to be developed in more than 20 years and offered hope for many patients, some of whom had suffered debilitating side effects from other available treatment options. However, on 24 December 2009, NICE recommended that the drug should not be approved for the treatment of non-permanent atrial fibrillation. This was justified by NICE on the grounds of cost and was greeted with widespread dismay from clinicians, patients, and their carers who believed that the drug's approval would be a useful alternative and an important addition to the few drug treatments that were previously available to clinicians. Shortly after the initial guidance was published, organizations including A-A and AFA

launched an appeal against the decision. A number of approaches were used, utilizing both patient and clinical support, targeting key stakeholders, including members of parliament (MPs), peers, and government officials within the Department of Health, and ultimately making direct appeals to NICE through appropriate channels.

The first activity was to motivate patient members through a series of 'Make Your Voice Heard' emails and letters which were sent to 8000 charity members. Both forms of communication allowed the organizations to reach a far wider audience, informing them of the decision taken by NICE and advising them of how they could play a part in possibly revising the decision, ensuring that they would be offered more treatment options in the future. Arrhythmia Alliance and AFA drafted letters for patients to send to their local MP and the Chair of the NICE appraisal committee. Patients were asked to tailor the letters as much as possible, writing about their own experiences so that decision makers were able to see the many ways in which this new treatment option would be of benefit. In all, around 1300 members wrote to NICE, MPs, and the Secretary of State for Health. Arrhythmia Alliance also wanted to ensure that clinicians' views were heard. A letter was written for clinicians to sign and send to NICE. This open letter, signed by 187 health-care professionals, raised a number of clinical arguments, which complemented the views of patients. Through further engagement with patient members, a series of patient and carer stories were used to highlight the need for the anti-arrhythmic drug to be approved. This fourteen page dossier of patient quotes and anecdotes further endorsed the key messages, again bringing a patient's perspective on how their quality of life is affected by current treatment options. These activities supported the formal submission to NICE made by the organizations on behalf of all their members.

In addition to lobbying decision makers, both within NICE and the Department of Health, MPs and Peers were targeted in order to rally additional support from within Parliament. Selected parliamentarians interested in health issues were approached. These letters were then followed by one-to-one meetings, so that the organizations could provide an in-depth briefing on both the condition and the drug itself. Briefing materials were also produced for these parliamentarians, which would allow them to refer to the issues if a relevant parliamentary debate occurred. Members of parliament and peers also wrote to the Chair of the NICE appraisal committee. Key MP advocates, such as A-A's local MP, tabled an Early Day Motion, as a statement demonstrating political support and acting as a signpost for other parliamentarians wishing to assist their constituents with the campaign. This work in Parliament complemented a Parliamentary and Stakeholder Investigation Report. Arrhythmia Alliance and AFA organized a meeting in parliament chaired by two MPs and attended by both patients and clinicians. The meeting highlighted the importance of approving new treatment options. The meeting was transcribed and resulted in a report, which was submitted to NICE. Patient witnesses gave evidence to the NICE appraisal committee, ensuring that the views of the patient organizations and their members were taken on board by committee members.

This seven month campaign led to the announcement that NICE would approve the use of the new anti-arrhythmic drug, for a

broad proportion of patients with atrial fibrillation. The appraisal committee concluded that this treatment option can, and should, occupy a currently vacant place in the care pathway, and that for a large and growing number of patients it could represent the only treatment option open to them. The announcement was welcomed by both members and clinicians, who had campaigned hard for this final decision.

While a decision like this may have appeared to be the final stage in the campaign, there was still more work that was needed to be done, not least in educating both patients and clinicians. To raise the profile of this important announcement further, the patient organizations worked with the media to report the decision nationally, while at the same time raising awareness among the general public of the condition. This high-profile decision by NICE provided a unique opportunity to utilize the media to report on arrhythmias, as they had traditionally been overshadowed by other conditions, such as cancer. Alongside this work, the organization also produced a leaflet for patients, explaining the decision, providing details of the drug, and highlighting the patient's right to receive the new treatment. A leaflet was also produced for clinicians, who may have otherwise missed the decision or were unsure of the new guidelines and the role that the drug could play in the patient's life. Although for many this signalled a successful end to a high-profile campaign, for A-A and AFA, it represented a breakthrough in the overall awareness campaign, which must now take on a different tone in order to push cardiac arrhythmias higher up the health agenda.

A new era of campaigning is now beginning, which coincides with a new coalition government, and a new, radical health agenda outlining an ambitious programme of reform for the National Health Service (NHS). Arrhythmia Alliance will now begin the process of engaging with a new intake of MPs to raise awareness of arrhythmias. The parliamentary awareness campaign assists the work of the organization in positioning the condition higher up the health agenda, ensuring that it is seen as a priority area. In addition to this work, the organization will further utilize its membership base to produce a patient charter, consisting of key calls for action, to be sent to ministers and officials, MPs, peers, primary care trusts (PCTs), and general practitioners (GPs). Arrhythmia Alliance, like other patient groups, has also made a formal submission to NICE suggesting atrial fibrillation as a topic for Quality and Outcomes Framework (QOF) indicators – a method of reimbursement to GPs to improve overall quality of care. Arrhythmia Alliance will also host a day dedicated to raising awareness of arrhythmias to MPs and their constituents to make representations to their local PCT to prioritize the condition. Each activity will play its role in ensuring that cardiac arrhythmias are seen as a priority by key decision makers.

The views of patients are central to any patient association campaign. Without this, organizations cannot legitimately put pressure on national health systems to adopt certain recommendations. The campaign for the review of the new anti-arrhythmic drug was only achieved because of charity members, and their drive for change. At all times during the campaign, the quality and value of life of patients were at the heart of discussions, as it is essential that these are at the centre of any decision. Case stories of patient experiences help create a clear picture for decision makers and

the wider public, who can sometimes struggle to take into account the effects of the condition without having experienced it themselves. It is clear that the role of the membership base of patient groups is evolving, and with developments in technology and with a greater media presence, this will no doubt increase further.

Patients groups not only represent the views of patients, they also have a duty to provide them with up-to-date information about advances in medicines, changes to the way services are run, and the implications these could have on their treatment. They provide a first port-of-call for many patients who have been diagnosed with disease, as well as their family members and carers. This information can be vital in allowing patients to navigate the health system, often seen as a complex area. As with A-A, many groups choose to legitimize their role with NHS or government endorsement; this both strengthens the position of the patient group as well as providing a 'kitemark' standard for their information documents. The links that patient groups have with clinicians can also assist patients with identifying a specialist in their region, ensuring that they receive the best possible care and treatment available. This unique 'agent' position of the patient group can also raise awareness of key events, such as conferences and educational seminars, which require both patient and clinical input. Although great strides have been made to strengthen the role of patient groups in providing a 'signposting' role, much more work needs to be done. This is an area in which A-A will be developing its own patient charter, to further raise awareness of arrhythmias and ensure their priority on the national health agenda.

From time to time, patients, doctors, or other health-care workers identify issues related to equity of access to healthcare, or the failure of a particular service which is supposed to be provided. In such cases, a patient group should intercede with the health-care providers to inform the system of its failure and to encourage its rectification. Important aspects of healthcare can be axed intentionally, or in error, and if this is not promptly recognized the service may default permanently. Often, an association must petition for the establishment of patient care services where they do not exist. In order to facilitate this aspect of its work, the group must have access to accurate and comprehensive information which it can obtain by careful accrual of data from its diverse membership. Persuading the chief executives of health-care providers to change their policy may be challenging, but much can be achieved by lobbying public interest, galvanizing local support, and importing the skills of experienced health-care workers and politicians. High-profile public campaigns may sometimes be needed but these should be used sparingly.

In order that patient associations prosper, there must be 'a will (enthusiasm) and a way (funding)'. The leaders of patient groups are generally self-appointed because it is their energy and enthusiasm which motivates the emergence of the group. As the group develops, other people must be enrolled to provide extra help. Patients and carers often give their time to this process but eventually professional paid staff is needed. When this occurs the funding issue becomes paramount, and there are no easy solutions to funding these organizations. Patients and carers may contribute themselves but such donations are rarely substantial.

A membership fee of some sort can be helpful, although this may prevent from joining many who would like to belong to the enterprise. Philanthropic gifts, covenants, and charitable donations with tax incentives are welcome but rarely available when an association is newly formed and its achievements only nascent. Some finance can be obtained from web site advertising revenue, sales of products manufactured by the group, fees from the lawful use of databases constructed and maintained by the association, etc. Some associations can earn from assisting government and may obtain research/service grants from health-care providers or large disease-specific charities. However, the 'elephant in the room' which is tempting but potentially hazardous is soliciting funds or accepting paid commissions from industry. It should be a self-evident rule for any patient association that it should have a mission statement and a detailed set of operating procedures in which it is clearly stated that no industry funds can be accepted unless the association is free to spend the funds directly in support of its mission. At times the intentions of industry and the mission of an association may coincide, in which case funds may be acceptable, provided that there is no contract or 'understanding' that specifies the way in which funds can be spent. Industry support may be a poisoned chalice that invalidates the authority of a patient association. This must be carefully guarded to ensure the legitimacy and respect of the association.

Patient associations and their alliance with other similar groups, health-care workers, providers and payers of healthcare, and medical commerce in general, works highly effectively without large contributions of funds from government. These organizations act to ensure equity of access to medical care, encourage patients and carers to take an active interest in their disease and contribute to its management, and improve overall medical, social, and psychological outcomes. To a very large extent these groups are self-funded and, if in receipt of donations from potentially conflicted sources they adhere closely to their mission statements and eschew being drawn into issues which are essentially commercial in nature. The patient must remain at the centre of the work of

any patient and carer organization and the group must work in collaboration with others members of the health-care community to ensure that services with both excellent benefit-risk and cost-benefit are made available to those who suffer from disease. Patient groups, for example the A-A or the AFA are part of the 'Big Society' where individuals help themselves and others without the need for the state and little thought of reward.

Conflict of interest: A.J.C. is an advisor to sanofi aventis, Merck, Boehringer Ingelheim, Bayer, and Daiichi.

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Addendum

Arrhythmia Alliance has established an International Toolkit as a practical guide for the process of establishing an A-A national model. Arrhythmia Alliance provides an international database of specialists, booklets, and factsheets relating to the diagnosis, treatment, and management of patients and CD toolkits with copies of all publications, including care pathways, medical papers, and job descriptions.