Clinical Microbiology and Infection 22 (2016) S146–S153

Contents lists available at ScienceDirect

Clinical Microbiology and Infection

journal homepage: www.clinicalmicrobiologyandinfection.com

Original article

The importance of the patient voice in vaccination and vaccine safety—are we listening?

D. Holt [1,2], F. Bouder [2,3,*], C. Elemuwa [2,4], G. Gaedicke [2,5], A. Khamesipour [2,6], B. Kisler [2,7], S. Kochhar [2,8], R. Kutalek [2,9], W. Maurer [2,9], P. Obermeier [2,10], L. Seeber [2,10], B. Trusko [2,11], S. Gould [12], B. Rath [2,10,*]

[1] *Confederation of Meningitis Organizations, Kerhars, Le Haut Corlay, France*
[2] *The Vienna Vaccine Safety Initiative, Berlin, Germany*
[3] *Department of Technology and Society Studies, Maastricht University, Maastricht, The Netherlands*
[4] *National Primary Healthcare Development Agency (NPHCDA), Abuja, Nigeria*
[5] *Department of Paediatrics and Adolescent Medicine, University of Innsbruck, Austria*
[6] *Centre for Research & Training in Skin Diseases & Leprosy, Tehran University of Medical Sciences, Tehran, Iran*
[7] *Clinical Data Interchange Standards Consortium, Austin, TX, USA*
[8] *Global Healthcare Consulting, New Delhi, India*
[9] *Department of General Practice and Family Medicine, Centre for Public Health, Medical University of Vienna, Austria*
[10] *Department of Paediatrics, Charité University Medical Centre, Berlin, Germany*
[11] *International Association of Innovation Professionals, Sugar Land, TX, USA*
[12] *SJG Consultancy, Lyon, France*

ARTICLE INFO

Article history:
Received 25 April 2016
Received in revised form
14 September 2016
Accepted 28 September 2016
Available online 6 December 2016

Editor: I. Gyssens

Keywords:
Cultural competency
Outcomes research
Patient advocacy
Patient empowerment
Patient voice
Precision medicine
Risk–benefit
Student education
User-centred research
Vaccines

ABSTRACT

Much has been written about the patient–physician relationship over the years. This relationship is essential in maintaining trust in the complex arena of modern diagnostic techniques, treatment and prevention, including vaccines and vaccine safety. However, a great deal of this material was written from the viewpoint of clinicians and academics. The patient voice may be positive or negative, fragmented or complex. Information sources are weighed and treated differently, according to the value system and risk perceptions of the individual. In post-trust societies, when people have less confidence in health authorities, communication needs to be more than a paternalistic top–down process. Notions of empowerment and individual patient choice are becoming crucial in medical care. The ‘voice of the patient’, which includes healthy individuals receiving vaccines, needs to be heard, considered and addressed. With respect to childhood immunizations, this will be the voice of the parent or caregiver. The key to addressing any concerns could be to listen more and to develop a communication style that is trust-based and science-informed. Regulatory agencies are encouraging clinical and patient-reported outcomes research under the umbrella of personalized medicine, and this is an important step forward. This paper attempts to reflect the paradigm shift towards increasing attention to the patient voice in vaccination and vaccine safety. **D. Holt, CMI 2016;22:S146**

Introduction

Vaccination remains one of the most efficient tools for reducing the burden of infectious diseases and safeguarding health. However, there have been concerns about vaccine safety [1], which may have an impact on vaccine acceptance. Vaccines are obligatory in many countries and recommended in others; hence, they are managed in a paternalistic manner. But patients and vaccine recipients have the right to make informed decisions. We are also living in a ‘post-trust’ environment [2,3], which means that the public no longer puts faith in the regulators or industry without questioning. It is not only the voice of the expert that is heard. Information can be disseminated through social media quickly and globally, with no checks on accuracy or on how this information may be used or interpreted [1,4].

---

[*] Corresponding authors. F. Bouder, Maastricht University, The Netherlands; B. Rath, Vienna Vaccine Safety Initiative, Berlin, Germany.

E-mail addresses: f.bouder@maastrichtuniversity.nl (F. Bouder), Barbara.Rath@gmail.com (B. Rath).

http://dx.doi.org/10.1016/j.cmi.2016.09.027

The public perceives risk differently from experts, and these differences may contribute to increasing vaccine hesitancy. Healthcare professionals (HCPs) can play a key role in vaccination and to do so, need to develop risk communication strategies that build trust.

This includes active listening techniques, to understand how others are assessing and perceiving risk, and to use this information to encourage better informed decisions.

This paper attempts to reflect the paradigm shift towards increasing attention to the patient voice in vaccination and vaccine safety and looks at how listening to the patient voice is key in any risk communication strategy.

There is a need to develop proactive risk communication strategies that work both ways, that is to say build up trust between medical experts and patients, and vice versa. Patients are not experts in the field of vaccines or risk assessments. Communication needs to be clear and concise, without complicated jargon and allowing questions and seeking feedback regularly. HCPs need to hear the patients.

The patient may voice subjective concerns and perceptions. Experts who understand and address these concepts will be able to ensure that important messages are not lost or ‘lingering in the air’ causing confusion.

Regulatory agencies are encouraging patient empowerment; for example, the European Medicines Agency is providing direct access to information for those who request it [5]. This approach provides additional transparency, which can help to build trust [6]. Recent work by Scherer *et al.* assessing the effect of safety information, showed that a concise summary can be useful, but too much detail (i.e. the detailed version of the Vaccine Adverse Reporting System) may have an adverse effect on vaccine acceptance [7]. Vaccine information is often technical, complex and difficult for a layperson to interpret, but if HCPs accessed this information to update their own knowledge, it could subsequently be used in two-way discussions with patients.

Meeting the objective of proactive communication requires going beyond information disclosure and forging a true alliance between vaccine recipients and/or their parents, patient organizations and HCPs [8,9]. Stronger individual and institutional relationships may be the right avenue to maintaining or restoring trust in public health and regulatory agencies, through which evidence-based vaccine safety information is delivered [10,11].

It is recognized that the ‘patient voice’ is a complex and far-reaching subject that can only be covered as an overview in its entirety. It may help to remember that both HCPs and patients share a common goal: to prevent illness while maintaining health. Avoiding unnecessary conflicts due to misunderstandings and establishing what Fischhoff and Scheufele call ‘fewer but better conflicts’ [9] will help to mitigate the polarizing effects of ‘vaccine controversies’ while maintaining a stable line of communication between patients and HCPs.

Who are the patients and what influences the patient voice?

The term ‘patients’ in this article extends to vaccine recipients and/or parents of vaccine recipients when the recipients are children. They are identifiable partners in the vaccine debate because they are recipients of a medical intervention, even though most vaccine recipients are healthy. In practice, patients may be exposed to many different vaccines, as either adults or children, and may speak on their own behalf or on behalf of patient organizations. As a consequence of different patient guises, a wide range of voices may be heard.

The patient voice will be influenced by various individual filters and perceptions. Psychometric risk studies of risk perception identified a set of variables to help explain how people perceive risks, demonstrating that people worry up to a thousand times more about involuntary risks (for example being forced to live next to a cell phone tower) compared with a voluntary risk (e.g. using a cell phone), and accept more easily risks that they feel in control of (e.g. driving a car) compared with those they feel not in control of (e.g. being flown in an airplane). They also showed that people worry more about unfamiliar risks (e.g. bird flu) compared with familiar ones (e.g. seasonal flu) and are more concerned about high-kill-size risks (e.g. airplane accidents) versus low-kill-size ones (e.g. car accidents) [12,13].

Specific to vaccine-risk perception, early accounts suggested that vaccines were perceived as only moderately unknown or dreaded. People's perceptions of vaccines were comparable to those for aspirin as opposed to antibiotics or DNA technology [13]. With the rapid advancement of vaccine research and development, as well as manufacturing technologies, this may have changed.

Specific to health and illness, key perception drivers include, for example, the high/low prevalence of a disease [14], perceived risk frequencies, availability and comprehensiveness of information, perceived dilemmas and ambiguities regarding how to interpret information, and the consequences for decisions to vaccinate or not, in addition to freeloading versus altruistic feelings [15–18]. Personal views and choices may be further influenced by levels of confidence and trust in institutions, complacency and, sometimes, personal convenience [19,20].

Attitudes, beliefs and behaviours that indicate concerns about vaccine safety have been shown to contribute substantially to under-immunization in the USA [21]. Studies by Flynn and Ogden [21] and by Downs *et al.* [22] on vaccination showed how parents are trying to take into account complex and contradictory concerns as they have mixed feelings about the medical profession and the media – for example when taking into consideration the risk of the measles, mumps, rubella (MMR) vaccination versus the risk of related illnesses [21]. These studies also highlight the concerns that parents may have in deliberating about vaccination, and it was noted that if health workers understand the parents' concerns, it is easier for them to address these concerns directly and help patients to make better informed decisions [22]. The studies in MMR vaccination also showed how past vaccination histories play a role in the decision-making process. If healthcare practitioners can address the concerns at the early vaccination time slots, this will benefit the uptake rate for later vaccination schedules [21].

Finally, these studies illustrated the gap between concerns identified among parents—i.e. for adverse and longer-term effects—and the confidence among experts in the safety of vaccines [21,23].

Fostering two-way communication partnerships: the central role of the HCP

The physician–patient relationship has been much discussed in modern medical literature and according to Goold and Lipkin it is the subject of some 8000 articles [24]. The essence of the relationship has a direct correlation with quality of care as a central feature of modern health care, which enables direct risk communication [4,24,25]. A large European survey ($n = 5648$) confirmed that people expect individualized safety information to be communicated to them and that HCPs are seen as the main trustworthy source of information [26].

The role of HCPs is essential in a patient/healthcare relationship. Downs *et al.* pointed out that many parents lack basic knowledge on how vaccines work and find the standard information provided unhelpful [22]. He also noted that those with the highest need seem to be the most vulnerable when it comes to confusing information