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Embedding '*Speaking Up*' into Systems for Safe Healthcare Product Development and Marketing Surveillance

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Abstract

Robust, active cooperation, and effective, open communication between all stakeholders is essential for ensuring regulatory compliance and healthcare product safety; avoiding the necessity for whistle-blowing; and, most essentially, meeting the transparency requirements of public trust.

The focus here is on what can be done within a healthcare product organization (HPO) to achieve actionable, sustainable policies and practices such as leadership, management, and supervision role-modelling of best practice; ongoing process review and improvements in every department; protection of those who report concerns through robust policies endorsed at Board level throughout an organization to eliminate the fear of retaliation; training in open, non-defensive team-working principles; and mediation structure and process for resolution of differences of opinion or interpretation of contradictory and volatile data.

Based on analyses of other safety systems, workplace silence and interpersonal breakdowns are warning signs of defective systems underlying poor compliance and compromising safety. Remedying the situation requires attention to the root causes underlying such symptoms of dysfunction, especially the human factor, i.e. those factors that influence human performance. It is essential that leadership and management listen to employees' concerns about systems and processes, assess them impartially and reward contributions that improve safety.

Fundamentally, the safety, transparency, and trustworthiness of HPOs, both commercial and regulatory, can be judged by the extent of the freedom of their staff to 'speak up' when the time is right. This, in turn, consolidates the trust of external stakeholders in the safety of a system and its products. The promotion of 'speaking up' in an organization provides an important safeguard against the risk of poor compliance and the undermining of societal confidence in the safety of healthcare products.

1. Introduction

For well over a decade, the healthcare product sector (including pharmaceuticals and devices, as well as regulatory agencies) has been plagued by high-profile safety crises, the investigation of which often lack transparency. A few investigations, such as that commissioned and published by Bayer,[1]

illustrate how unsafe human performance within a pervasive blame culture inhibits speaking up about safety concerns. More recently, the US FDA published an investigation into a contract research organization (Cetero),[2] which began after an employee raised formal allegations of regulatory violations and other misconduct. The employee claims to have first voiced concerns to management in June 2007, but it was not until April 2009 that the company arranged its own internal investigation.

By 'speaking up' we mean the voluntary act of speaking openly and frankly to peers or senior management about any problems or concerns that an individual might have about any aspect of their organization or their work, particularly when they believe issues of safety are at stake.

The challenge of 'speaking up' is not limited to commercial healthcare product organizations (HPOs) but affects all involved with healthcare products.

The authors of a 2006 Institute of Medicine (IoM) report entitled *The Future of Drug Safety* were concerned about the poor quality of safety culture within the FDA.[3] While there has been significant organizational change at the FDA since the report, details have not been publicized as to what changes have been made specifically relating to how the agency is encouraging 'speaking up'. Indeed, experts within at least one of the Centers within the FDA have raised serious concerns about decision making, and suppression of conversations prior to decision making.[4]

Within the EU, in an open meeting about clinical trial pharmacovigilance, it was candidly acknowledged that fear undermined 'speaking up' about inadequacies of the current system, and hindered a rational interpretation of regulatory requirements.[5]

The most extreme method of 'speaking up' in any organizational setting is whistle-blowing, the need for which itself demonstrates a profound failure of safety culture.

An assessment of pharmaceutical whistle-blowers concluded the following: about 82% of these pharmaceutical manufacturer employees who become whistle-blowers (usually filing a complaint about defrauding healthcare reimbursement) led to unwanted pressures from their employer, including being fired, intimidated or blackballed. Along with the stress of participating in a protracted investigation (the average case lasted almost 5 years), whistle-blowers reported financial difficulties, personal hardships and stress-related health problems.[6]

Despite a steady stream of pharmaceutical whistle-blowers, primarily in the US, analysis appears to be lacking as to why some employees have sought this last resort and whether or not their company had any policies or processes for 'speaking up', which, even if existing, were obviously not respected or enforced.

The UK National Health Service (NHS) approach, in contrast, has made whistle-blowing official policy, using it as a practical governance tool to deter wrongdoing and raise the bar on safety standards and quality.[7] Regrettably, inadequate systemic change continues to severely hinder 'speaking up' within the UK NHS.[8,9]

Workplace silence and interpersonal breakdowns have consistently been found to be symptomatic of dysfunctional safety management systems in business and regulatory settings beyond the healthcare product sector.[10,11] There are successful sectors where 'speaking up' is encouraged, alerting leadership and management to deficiencies, thereby accruing an impressive safety record.[12-15] However, in contrast to the wealth of safety culture and safety management literature, and evidence from other areas of industry and society, there does not appear to be any published evidence as to how HPOs, commercial or non-commercial (such as regulatory agencies), systematically encourage 'speaking up'.

While many HPOs have built extensive ethics and compliance infrastructures, including helplines, ethics codes and training schemes that detail how to report misconduct, despite this good intent, the onus has remained on the individual rather than focusing on the system and essential cultural changes needed to empower and motivate individuals and to facilitate 'speaking up'. HPO managers may say that they want to hear from their staff, but the importance of actively promoting and implementing systemic change is not sufficiently appreciated to generate policy and behavioural change.

When something goes wrong within an HPO to compromise safety, the counterproductive temptation to assign fault and/or punishment is best replaced with re-evaluation, education and learning, ideally shared widely with others across the sector. Progress has been made in creating more open, blame-free cultures to address root causes of error within healthcare. Both healthcare and HPOs share many of the same organizational and management issues, problems and solutions. Therefore, HPOs should be able to learn efficiently from the ongoing progress in institutional healthcare safety.[16]

2. Human Factors that Interfere

2.1 Why Intelligent and Committed Scientists and Physicians find it so Difficult to Speak Up

Humans working within a system are characterized by sociological and psychological complexities. Disappointingly, orientation, education and development within the pharmaceutical sector in particular frequently depend on rigid or vague processes rather than on the components of team development, management, communications and leadership within the scientific and regulatory content of pharmacovigilance curricula designed to promote 'speaking up'.

All the more worrying is when decisions about safety, such as signal detection and benefit-risk assessment, depend so much more on judgement than facts.

Any fears humans have of 'speaking up' coupled with a prevailing blame-oriented environment profoundly undermine safety.[17] Human factors that are personal affect all of us to variable degrees, and influence a willingness to 'speak up' – such as caution, uncertainty, lack of self-confidence, fear, self-interest, laziness, desire for a quiet life, lack of inhibition about bending the rules, desire to please, ambition and conscientiousness.

In many cultures there are also societal values that act against 'speaking up', making the experience not only profoundly threatening but personally distressing. This is especially true given the current economic climate and the threat to job security. The barriers to 'speaking up' are compounded in certain societies (as in Asia) where status, deference and 'losing face' are powerful influences determining behaviour.

These combined human factors impacting safety are also affected by organizational history and traditions. Some organizations have a history of oppressive employee relationships, with management by fear, even bullying. Use of financial penalties for staff when audits reveal non-compliance is simply one illustration. For such HPOs, it will take genuinely radical change to create an environment to promote 'speaking up'. The challenges of getting those in senior positions in such HPOs to listen, to accept criticism and to welcome uncomfortable opinions require fundamental reform.

Such fundamental reform might be called 'enlightened self-conversion' as it encompasses processes of immense subtlety and complexity, which may appear to be a threat to the self-image and traditional authority of leaders and, especially, senior managers. Codes and procedures will achieve little if there is not a thoroughgoing intellectual and psychological 'conversion' to the values of openness, honesty and mutual respect in organizational relations. This is a subtle and complex dimension to the oft-promoted transparency of business conduct. This is a move from assertive confidence to attentive humility in the face of complex issues, of competence moving from an exclusive concern with delivering traditionally satisfactory results to include the open and intelligent recognition and management of the uncertain and the unexpected. It is the humane coaching of employees to feel safe and valued to reduce the interference of damaging psychological factors.

2.2 What is needed to Reform Organizational Safety Culture and Systems to Facilitate 'Speaking Up'?

To achieve an effective system to facilitate 'speaking up', processes need to be designed to encourage willing, prompt and early reporting of problems by anyone who works within the system. Below are highlights for such reform.

2.2.1 Determining 'Operational Sensitivity' and Setting Priorities

'Operational sensitivity' refers to facing the reality of what actually happens in a process to

define operational needs. Thus design, implementation and improvement of a process requires assessment of human performance, taking into account staffing levels, morale, motivation, actual skills of those involved, training strategies, human technology interfaces and other human system interfaces such as the quality of teamworking.

Safety priorities need to be actively and visibly aligned with organizational vision and mission for a just, safe and socially responsible HPO. However, unless a vibrant underpinning culture of 'speaking up' exists, safety decision makers will be discouraged from making bold and innovative choices for fear of being blamed personally, even if the decision was made in good faith.[18]

2.2.2 Promoting Safety by Leading Through Productive Rather than Counterproductive Example

Those with responsibility for the success of safety evaluation must demonstrate focused leadership and have enough time and political clout to exercise it effectively.[12,15] Those in charge need to actively and visibly convey that safety is a priority, not merely as an ideal but as a gritty working principle. This entails conveying that those with responsibility are open, interested, and willing to act when 'speaking up' occurs and that they appreciate frank conversations. The strongest leader is one who actively solicits feedback, initiating such conversations. Only such firm, explicit leadership will stimulate employees to speak. Within that context, what appears to be risk-taking is actually effective risk management, not only on the part of leadership but also on the part of colleagues at all levels of responsibility.

Leading by productive example includes contractual protection that is visibly enforced for those who 'speak up' and willingly engage in difficult conversations. Conversely, where subordinates perceive leaders' behaviour as unwilling to protect those who 'speak up', or indicative that it is either unsafe or futile to do so (what we refer to as 'leadership by counterproductive example'), they will be discouraged to 'speak up'.[19]

The specific attitudes and behaviour of leaders will deeply influence how others feel and respond. The degree of openness and staff confidence in the commitment to transparency within an organization's culture will influence how much they will be prepared to 'speak up'. The culture will also determine the extent to which immediate and frank upward input is encouraged through face-to-face encounters or meetings. Suggestion boxes or surveys (of the live, active and responsive type) are useful secondary methods of communication for situations not requiring urgent attention and to monitor the systemic safety climate.

2.2.3 Recognizing the Inevitability of Process Deviation and need for Continuous Improvement to Manage Change and Errors: Coping with Organizational Silence

Rolling out effective and efficient processes requires vigilance not only for errors and problems in human performance but also exceptions and weak points in a process that can be highlighted for analysis and resolution. Fear of 'speaking up' and making errors contribute to 'work-arounds' – improvised methods to circumvent an obstacle (often outside the standard operating procedure [SOP] process), but which do not eliminate the obstacle.[20] Such intentional SOP violations may well appear justifiable as they meet the immediate need of dealing with obstacles as they arise in the demands of the moment. A robust safety system tracks such deviations and adjusts processes appropriately through continuous quality monitoring and improvement.

Unfortunately, without 'speaking up', obstacles are not brought into the open and improvements that would prevent the same problem recurring may never be made. Repeated 'work-arounds' not only become dangerously routine but lead to employee burnout because of the stress involved.[20] Effective management rewards the initiation of difficult conversations that contribute to rigorous safety analysis and procedures; seeks to understand why violations may occur; and provides coaching and protective support structures to motivate employees to 'speak up'.

Organization-wide information campaigns encouraging process improvement and conveying safety priorities can play an important part. Staff need to be encouraged and trained to solve problems as they arise, manage their own errors

and inform managers of solutions. In other industries, most notably aviation, 'speaking up' is intrinsically part of the regular and routine use of operational cross-checks (including checklists and debriefings) and other reporting processes to gain objective feedback from those who work in the system.[12,14] Through 'speaking up', management gets the necessary feedback to monitor these changes and act to modify processes as part of continuous improvement. As problems arise (in contrast to letting them accumulate), policy and processes need to be adapted in a timely and visible fashion to maintain confidence of the teams involved.[21,22]

Management need to be wary, in particular, of organizational silence – 'a collective-level phenomenon of saying or doing very little in response to significant problems that face an organization'.[23,24] Early definitions of 'silence' equated it with 'loyalty' and the assumption that nothing was wrong if concerns were not being voiced. But researchers today have shown that a climate of silence can seriously compromise desired organizational outcomes.

2.2.4 Protecting Employees Who 'Speak Up'

Employees not only need to be reminded of their responsibility to come forward but also be assured that they are protected from adverse criticism or punishment. A work environment that creates free and open lines of communication both up and down the chain of command provides a climate that supports the development of personal responsibility and lessens the risk from systemic intimidation, especially in a global HPO.

Robust internal mediation structures both supports 'speaking up' and provides a mechanism to protect employees from direct and indirect threats. One approach successful in military settings might be adapted to HPOs. This involves creation of an after-action review coordinator role as part of quality management. An after-action review is a professional discussion of a particularly significant organizational event (e.g. a compliance failure or debrief after a team has implemented a new process), focusing on performance standards. This formalized 'lessons learned' approach enables the team to discover for themselves what happened, why it happened, and how to sustain strengths and remedy weaknesses.[25]

A formal Safety Ombudsman might also be implemented for a large HPO, especially if global or operating across multiple jurisdictions. This internally well publicized role would report to the Board of Directors (ideally a Committee composed of outside Directors). Such a role serves to gather and research safety complaints (including those that are anonymous), which would then be resolved in mediation sessions. This process needs to be removed from the hands of all supervisors and requires well trained and independent mediators. Such a role can supervise the implementation of contracts that protect employees from retaliation and repercussions after 'speaking up'. Such an approach may help restore public trust, especially in those HPOs that are large, complex organizations, because of its transparency.

2.2.5 Increasing Emphasis on Quality of Development Activities and Impacts

Development activities – from new employee orientations through specialized and/or ongoing training – are made credible and justifiable through leadership endorsement and encouragement. An engaging, motivating tone of presentation and high level of group interactivity improves comprehension. To ensure the thoroughgoing commitment of those involved, training needs to include the safety-related decision-making flow process, with case illustrations that feature shared responsibilities throughout the organization and that demythologize the safety function as the province only of only one particular department.

Case examples of failures (internal and external) as well as successes can provide meaningful exercises of deliberation within the training. External examples can include those from other industries as well.

Furthermore, an approach dominated by SOPs and an attitude that one size fits all needs modification. To understand how a process works includes recognizing the importance of the influence of human factors, each task or step taking into account the actual working environment, interpersonal relationships and skills, time of day

and week the task is performed, hierarchical position of staff within the organization, technical complexity of the task as matched to individuals' abilities, and personal confidence of those involved, among other crucial dimensions. All too often, training (and execution) is more focused on the assumption that a process will not fail, rather than on the unpredictability of many processes and on how employees need to recognize hazards and threats to 'speaking up' in critical moments in order to draw attention to vulnerabilities and contribute to process redesign.

2.2.6 Creating Codes of Ethics and Professional Standards, Including Best Practices

Individuals can and must achieve a sense of allegiance to codes of ethics and professional standards that exceed the pressure for allegiance solely to the group or to the prevailing culture in which they work.

Translating codes and standards into action is a governance matter that all Boards need to examine closely and exert oversight influence throughout their organization and systems. A robust safety system would have a policy in place so that employees know when they can 'stop the line', to borrow a production model term. This policy would be developed to support an ethical culture in which staff can communicate freely to champion safety and take urgent action, if necessary, with or without other team members, when a healthcare product or system safety is compromised.[26]

3. Conclusions

Inherent in these six highlights for reform are the grounds (and content) for best practices, from those relating to operational sensitivity through development programmes of orientation and training to policies, procedures, codes and standards. Over time, the actual experiences can be captured and utilized in a variety of ways.

'Speaking up' about safety must be seen as a protected and worthwhile contribution to organizational health and development, and fundamental to managing the risks of a healthcare product – and rewarded appropriately, such as in the course of performance reviews and distributing bonuses, especially those tied to innovation contributions. Fundamentally, the safety and transparency of HPOs can be judged by the extent of the freedom and willingness of their staff to 'speak up' when the time is right. This, in turn, consolidates the trust of stakeholders, from investors to global audiences, in the safety of an HPO and the products for which it is accountable.

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