



**A Multidisciplinary Approach to Care for Obstructive Respiratory Conditions:
Communication, Coordination and Concordance
A Report by the IPAC-RS Patient Concordance Steering Committee**

Disclaimer: This paper reflects conclusions of the IPAC-RS Patient Concordance Steering Committee workshop and literature review. The inclusion of any recommendations or mention of any organizations or products does not represent endorsement by IPAC-RS or any IPAC-RS member company.

Background on the IPAC-RS Patient Concordance Steering Committee

The Patient Concordance Steering Committee (PCSC) of the International Pharmaceutical Aerosol Consortium on Regulation and Science (IPAC-RS), a panel of health professionals, patient advocates, and members of industry, was formed to investigate how adherence and concordance in asthma and COPD might be improved through collaborative efforts. During 2010-2012, the Committee held regular meetings and organized a public workshop to foster dialogue between patient advocates, health care professionals, payers, and industry. It also reviewed literature identified through PubMed using the keywords asthma, COPD, health literacy, compliance, adherence, concordance, communication, patient involvement, device selection, education, technique demonstration, and self-management. This report presents the Committee's findings and recommendations for improving concordance to address non-adherence. Although this work pertains largely to the United States healthcare system, some elements are globally relevant.

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Asthma and COPD: Global Burden of Disease and Need to Improve Adherence

Asthma and chronic obstructive pulmonary disease (COPD), combined, are the most common chronic lung diseases in the world.¹ Both are a product of genetic and environmental factors and result in significant morbidity, loss of work, impaired quality of life, and high healthcare costs.^{2,3,4} Asthma generally begins in childhood with acute episodes. COPD, on the other hand, results from smoking, secondhand smoke exposure, occupational exposures or genetics and typically progresses slowly. While COPD mortality continues to climb, asthma mortality in industrialized nations is slowly dropping. Improving treatment adherence presents an opportunity to reduce the burden of disease associated with asthma and COPD,

Patients have long been primarily responsible for care routines but had difficulty obtaining optimal outcomes, possibly because of insufficient knowledge or training about their disease, medication, inhaler technique, and/or treatment schedule; physical or cognitive ability; choices regarding treatment; or other factors. These factors can adversely impact medication adherence, “the extent to which a person’s behavior... corresponds with the agreed recommendations from a health care provider.”^{5,6,7,8(p.3)} Poor adherence and non-adherence are associated with worse control and widely acknowledged.^{8(p.24),9,10,11}

Recently, greater emphasis has been placed on a patient-focused, collaborative approach to improve adherence. Patient-centered care, characterized by involvement of the patient in care and the personalization of care, has been seen to promote adherence and better outcomes.¹² Concordance, which implies agreement on a therapeutic plan between patient and health care professionals and gives greater recognition to the patient’s perspective, has been discussed as a possibility for improving care.^{13,14} Increased coordination between health care professionals, researchers, health planners and policymakers has also been called for.^{8(p.24)}

Further implementation of a patient-centered approach to care in asthma and COPD that collaboratively engages health care professionals, families, caregivers, employers, health systems, pharmaceutical companies and regulatory authorities and encourages communication, education, and careful selection of devices to address patient needs may contribute to appropriate use, resulting in improved outcomes and reduced costs.

The Need for Mutual Understanding: Factors Affecting Patient Approaches to Care and the Role of Communication and Coordination

The experience of a physician who diagnoses a chronic respiratory disease is different from that of a patient who receives a diagnosis. Patients and physicians both seek information from each other and have similar goals but have different training, experience, and perceptions.¹⁵ Greater understanding of a patient can enable development of treatment plans that are well-suited to patients and ensure that sufficient instruction is provided. This understanding may be acquired through attention to factors that may affect a patient's approach to treatment as well as clear, consistent communication.

Many general factors can impact how a patient approaches treatment, including social/economic, health team/system-related, disease-related, therapy-related, and patient-related factors.^{16,8(p.27-30)} (L Fromer, MD, FAAFP, The Purchaser Perspective lecture at IPAC-RS Ensuring Patient Success: Improving Adherence through Concordance Workshop, March 2011). Health literacy and support systems - or lack thereof - are some of the socioeconomic factors that may affect adherence. Low health literacy has been associated with non-adherence; medication errors, including improper device use; and lack of knowledge about when to seek care.^{17,18} Patient-provider relationships, disease-related aspects, and therapy-related aspects are other potentially influential factors. Education, beliefs or attitudes about medication, perceptions and expectations can also affect adherence.^{19,20}

Patients with asthma and COPD may face specific challenges that impact their adherence. COPD patients may be impacted by multiple co-morbidities, with behavior affected by challenges with multiple medications, insidious onset of symptoms, acceptance of symptoms as part of aging, lack of immediate subjective response to inhaled medications, or exacerbations.^{21,22} (B Yawn, MD, MSc, FAAFP, From Compliance to Adherence to Concordance lecture at IPAC-RS Workshop, March 2011) They may also face cognitive impairment, depression, or anxiety in addition to age-related challenges such as impaired motor skills, loss of vision or hearing, and increased reliance on caregivers. Asthma patients may be challenged by a need for multiple therapies or the technique for using a device, which can be especially challenging for children.^{23,24} They may accept symptoms as "normal," or have trouble incorporating treatment into a busy lifestyle. Children and adolescents with asthma may lack the ability to determine when medication is needed, and rely on caregivers who may not know how and when to help them.²⁵

To elicit information and promote understanding, health care professionals and patients can seek to initiate productive, non-judgmental conversations and be clear, consistent communicators. Constructive, open dialogue can help health care professionals, patients, and families feel more comfortable discussing symptoms, behavior, challenges, and asking questions. (B Yawn, lecture, March 2011) This type of patient-centered communication can create positive perceptions of care, build confidence and trust, and increase the probability that the patient will follow treatment recommendations.^{26,27,28,29,30} This approach is preferred by many patients, who may desire greater involvement in care decisions, and can contribute to improvements in disease management.^{31,32,33,34}

Communication between health professionals is also important. The National Institutes of Health's Asthma Guidelines recommend that all patients receiving urgent care for asthma/anaphylaxis at any site should be assessed, receive explanations of care options, and be referred to appropriate primary and specialty care.³⁵ The Global Initiative for Chronic Obstructive Pulmonary Disease (GOLD) guidelines recommend that patients suspected of having COPD should be referred to a chest physician or pulmonologist for comprehensive evaluation and management, although most care for COPD is done by primary care physicians.³⁶ Communication amongst health care professionals can help ensure that each has relevant information and that the patient receives consistent, coordinated care and advice. Coordination within and between offices, emergency departments and hospitals facilitates efficient management of care. Support staff can help ask questions to elicit more information, and physician assistants and nurse practitioners working in partnership with physicians can be effective educators.³⁷ These approaches can create and maintain a well-informed and higher-functioning care team, with the patient acting as a central, active participant.

Equipping Patients for Success

With enhanced understanding of the patient's needs, health care professionals are better-equipped to develop an appropriate treatment plan. Device and medication selection should be based upon efficacy and safety but may also be informed by cost and insurance coverage. A variety of references that describe potential advantages and disadvantages of different devices for specific patients are available.^{38,39,40,41} Once a therapy has been selected, clear instruction and provision of tools can promote correct use.

Education about a therapy's name, purpose, treatment schedule, possible adverse events, and methods for recognizing if it works are recommended by the Agency for Healthcare Research and Quality to prevent medication errors and improve adherence.^{42,43} For inhalers, it is important that this information be complemented with demonstration to establish proper technique.^{44,45,46} Attention to the delivery of this information is crucial. Health professionals may omit important information, overwhelm patients with more information than they can absorb, or use medical jargon that is difficult for patients to understand.^{47,48} (N Sander, I Pledge Allegiance: A Patient's Perspective on Compliance, Adherence and What We Can Do About It, lecture at IPAC-RS Workshop, March 2011, Allergy and Asthma Network, Mothers of Asthmatics) Health professionals may also be unable to demonstrate proper device technique and need refresher education so that they can demonstrate correct technique.^{49,50} Failure to provide appropriate instruction to patients can invite poor adherence and technique, which can result in reduced disease control.^{51,52}

For some patients, supplementary design features, add-on devices, and training aids may be helpful in promoting correct use of devices. Dose counters help patients and caregivers monitor the amount of medication remaining and are recommended by the U.S. Food and Drug Administration for inclusion in all MDIs.⁵³ They can help patients avoid discarding devices too soon or continuing to use an empty device, which is especially problematic during an exacerbation.⁵⁴ Features that provide feedback, such as flow indicators that enable patients and caregivers to see or hear the movement of the inhalation valve, may increase confidence that medication is being delivered.^{55,56} For patients with pMDIs, the addition of an inhalation aid such as a spacer or holding chamber that is well-suited to the patient can ease the challenge of hand-inhalation coordination and improve drug delivery.⁵⁷ When additional instruction is needed, multimedia training tools such as digital media or web-based instruction may be considered.⁵⁸

Patients may also be provided with resources to guide them outside of the doctor's office. The National Heart, Lung, and Blood Institute Asthma and GOLD COPD Guidelines recommend the use of action plans that record the daily medications prescribed, help patients assess symptom severity, and guide actions during an exacerbation.^{35,36} These plans can enable self-management and contribute to improved outcomes in asthma, although they may be underutilized.^{35,59} (N Sander, lecture, March 2011) Action plans may be effective in COPD as well, but further study is needed.⁶⁰ Technology reminders, smart phone and tablet applications are also available to help patients monitor the status of their condition and its treatment.^{61,62}

At every office visit, health care professionals and patients can revisit instructions, reconcile medications, and discuss whether the patient's needs are being met. Repeated training is important to reinforce and improve technique, which can decline within days of initial instruction.^{63,64,65} Discussing symptom frequency, impact of symptoms on activity, triggers, and adherence can enable health care professional to assess the effectiveness of treatment.⁶⁶ Motivational interviewing, which entails discussion about how treatment aligns with a patient's lifestyle and goals, can be a time-effective method of increasing intrinsic motivation.⁶⁷ This is important because knowledge alone may not result in adherence.⁶⁸ Between office visits text and web messaging, email, and telephone consultations may be viable options for communication.^{69,70,71,72}

Care in the Context of a Larger Team: Pharmacists, Family and Caregivers, Employers and Health Plans

As chronic diseases, asthma and COPD routinely not only involve the patient and physician but also ancillary health care professionals, pharmacists, family members and caregivers, employers and health plans. As the patient transitions between health care visits, pharmacies, home, work, and school, these additional members of the care team play important roles in the evolution of care, access to care, receipt of medications, and education. By acting in concert, they may provide increased support to patients and facilitate more successful disease management.

Pharmacists play a vital role in delivery of medications because of the chronic nature of asthma and COPD. When providing medication, they can confirm that the patient is receiving what their healthcare professional prescribed or, in instances where pharmacy substitutions are allowed and a change has been made, alert the patient to the change and provide medication information and training. Through reinforcement of instructions and the importance of taking prescribed medications, pharmacists can help improve adherence and outcomes.^{73,74,75,76} However, published evidence suggests that although pharmacists recognize their important role in aiding patients, they may be unlikely to provide instruction due to lack of time, interest from patients, or demonstration tools.⁷⁷ They may also need training to be able to demonstrate proper technique.⁷⁸ Physicians and pharmacists may coordinate to ensure that the therapies physicians prescribe are kept in stock or check refill rates to monitor adherence.⁷⁹ Patients can

take an active role by confirming information with pharmacists, and following-up with physicians and/or other care team members about any medication changes.

Engagement of family and caregivers in care can positively impact adherence and the patient's quality of life, particularly for children and adolescents with asthma as well as COPD patients.^{80,81} When permitted, sharing information about the patient's condition and treatment with family and caregivers may enable them to provide positive reinforcement. For children, shared medical appointments involving caregivers can improve quality of care.⁸² Ancillary caregivers such as schoolteachers and disease-related support groups can reinforce education, a responsible approach toward disease management, and positive attitudes.^{83,84} However, limited knowledge about asthma and its management may limit their effectiveness.²⁵

Employers and health plans contribute to care by increasing accessibility of care and promoting wellness. Managed care plans can promote evidence-based guidelines, measure outcomes, target risks and impairments, and adapt to changes in understanding of asthma and COPD and their treatment.⁸⁵ Managed care organizations may also supply educational materials and outcome measurement tools.⁸⁶ Employers can contribute by sponsoring educational and wellness initiatives to reduce impairment and overall costs through better disease control.^{87,88} Better control can decrease absenteeism, decrease costs, and improve productivity, health outcomes, and quality of life.^{89,90,91}

Identifying and Addressing Non-Adherence

Regardless of the strength of the relationship between the patients and their health care professional; engagement of pharmacists, caregivers, and others; and/or the patient's commitment to their treatment, a patient may not take their medication as prescribed. Non-adherence may take multiple forms, unintentional (erratic adherence and unwitting non-adherence) and intentional (intelligent).⁹² (B Yawn, lecture, March 2011) Conversations with patients, medication reconciliations, and discussions with family members, where appropriate, can all identify adherence issues.⁵ When non-adherence arises, approaches tailored to a patient's specific needs are required.⁹³

Erratic adherence and unwitting non-adherence are both considered unintentional. Erratic adherence occurs when the patient understands and agrees with their therapeutic plan but has difficulty consistently maintaining the regimen. It may be caused by forgetfulness,

disorganization, a complex medication regimen that doesn't match the patient's lifestyle, changes to their schedule, running out of medicine, or day-to-day occurrences. Unwitting non-adherence occurs when the patient and clinician mistakenly believe that the patient is using the medication as the physician believes they prescribed. This often results because of miscommunication or misunderstanding. Patients may fail to correctly recall instructions, or be unable to read and understand written instructions. Asking the patient about their medication use and technique during subsequent visits, especially when refill requests do not match expectations, can help identify and address these issues.

Intelligent non-adherence is intentional and occurs when the patient deliberately alters or discontinues therapy. Intelligent non-adherence may occur when the patient does not understand or believe the chronic nature of their disease and stops or decreases medication when they are feeling "better" (or "cured"). This may happen because a patient doesn't understand how a medication works, or may be concerned about toxicity, perceived ineffectiveness of therapy (no acute symptom control), fear of developing "tolerance" to the medication, personal beliefs, or failure to link actions and consequences.

When non-adherence is recognized, appropriate interventions can be identified through assessment of the type of non-adherence and factors that contribute to it.^{8(p.31-35),21,94} Social and economic interventions can help address issues related to access, costs, health literacy, provision of support networks, and beliefs. Health care team and health system interventions can address lack of awareness, provision of clinical and behavioral tools, access to medications, and coordinated care for chronic conditions. Therapy-related interventions may address issues related to dose frequency and side-effects. Finally, interventions related to patient-specific factors may address lack of information and skills, motivation and self-efficacy, and behavioral changes. Self-management strategies have been proven effective in improving adherence in asthma and may be effective in COPD, although fewer studies have been conducted about COPD.⁹⁵

Meeting the Needs of the Patient in the Development of Inhalation Therapies: The Role of Industry and Regulatory Authorities

Patients rely heavily on inhalation devices for treatment of asthma and COPD. While communication, careful selection of devices, and instruction may diminish handling and inhalation errors, intuitive device designs, patient-friendly instructions and training tools may

further decrease potential for errors.⁴⁰ As a result, pharmaceutical and medical device companies as well as regulatory authorities can play an important role in promoting correct use of therapies and better adherence through design and approval of patient-friendly devices, instructions for use and education and management tools.

Patient-friendly device development can be promoted through the implementation of human factors assessments, which enable developers to better understand patients' needs and identify use-related hazards. These assessments are incorporated into the design and development process in the form of task analysis, creation of user profiles, risk analysis, cognitive walkthroughs, and other activities which contribute to the development of safer and more effective devices.⁹⁶ For human factors studies for inhalation devices, a focus on design aspects crucial to drug delivery is especially important for identification and reduction of critical use errors, which are errors that result in a clinically significant event such as not receiving a dose. For this reason, studies often include assessment of handling and the inhalation maneuver. Despite their utility, these studies can be limited by the fact that handling and technique are often assessed through observation so the clinical impact of poor technique may not be immediately apparent.

Regulatory authorities and international standards organizations can be instrumental in encouraging the use of human factors through the regulatory review process and the guidance they provide. These bodies have addressed human factors and usability engineering in a series of guidelines that apply to inhalation devices for asthma and COPD, including: the AAMI/ANSI HE75:2009, *Human Factors Engineering – Design of Medical Devices*, ISO/IEC 62366:2007, *Medical devices – Application of usability engineering to medical devices*, ANSI/AAMI/ISO 14971:2007, *Medical Devices – Application of risk management to medical devices*. Recent revision of a directive in Europe to focus specifically on risk-reduction and the FDA's 2011 release of draft guidance on human factors demonstrate the growing importance of human factors to health authorities.^{97,98} These guidance documents can be broad in scope – they can cover medical devices ranging from equipment for intensive care to spoons – and should be considered in the context of the disease state for which devices are used (e.g. acute/prophylactic, chronic/episodic), the setting in which they are used (e.g. clinical, non-clinical setting) and with regard to the target user group (i.e. health care professionals, pediatric patients, geriatric patients, etc). Nonetheless, they provide useful guides for the implementation of human factors.

Design and approval of clear, understandable Patient Instructions for Use (PIU) by pharmaceutical companies and regulatory authorities respectively may address use challenges and limited health literacy. Consideration of the U.S. Pharmacopeia's (USP) Health Literacy and Prescription Container Labeling Advisory Panel recommendations in development of instructions may help address patient misinterpretation or misunderstanding (although it should be noted that these were originally designed for medication labels). This panel recommended: patient-centered organization, use of simplified and preferred language, use of pictorial aids and explicit text to describe instructions, improved readability, and supplemental information.⁹⁹ Additionally, in 2011, the European Medicines Agency updated the template for package leaflets to make leaflets more readable, and provide more information about a medicine's benefits as well as use in children.¹⁰⁰ Pharmaceutical companies may also provide employees with training that equips them to apply health literacy principles when developing labeling or instructions, or conduct consumer testing to improve consumer medication information.¹⁰¹

Finally, user-friendly training and management tools developed by pharmaceutical companies and device manufacturers and approved by regulatory authorities may be a helpful resource. These may include placebo-filled devices that enable health care professionals to demonstrate device use as well as tools mentioned previously, including web-based training and pictorial guides, and applications to help the patient remain aware of their treatment status. Creating and making effective tools available can be challenging, however, because of the diverse needs of different patient populations and the length of the regulatory review process. (IPAC-RS workshop participants, March 2011, oral communication during Health Care Professional Breakout Session at IPAC-RS Ensuring Patient Success Conference)

Conclusion

Patients, health care professionals, families, caregivers, employers, health systems, pharmaceutical companies and device developers as well as regulatory authorities all contribute to patient care. An integrated, collaborative, patient-centered approach to care - which engages all of these participants with a patient's needs, disease education, medication and device use, and appropriate care transitions - has potential to improve concordance by improving communication and understanding. It may also help ensure that patient is an active participant in their care, and receives supplementary training and support which promote better outcomes.

The diversity of stakeholders and number of variables involved in collaborative approaches will make implementation and assessment of effectiveness challenging. Further study of individual components of such approaches is needed, as are larger studies which consider multiple sets of stakeholders and factors. Continued dialogue amongst multidisciplinary sets of stakeholders about these types of approaches is also needed. This will encourage shared understanding of the roles that each set of stakeholders play, the needs they have, and the challenges they face. Such understanding will help all stakeholders to understand their role in care relative to others, and may enable them to contribute more effectively to patient care.

Take-Home Points

- 1.** Asthma and COPD are prevalent respiratory diseases that result in significant morbidity, decreased quality of life, and high health care costs. These effects may be reduced through better disease control. However, many patients have difficulty achieving optimal control because of non-adherence related to insufficient knowledge or training about their disease and/or treatment; poor inhaler technique; physical or cognitive challenges; or choices regarding treatment and ability to follow a treatment schedule.
- 2.** Increased understanding of the patient can increase the ability of health care professionals and patients to develop appropriate treatment plans and training. This can be obtained through attention to factors that may influence a patient's approach to treatment and open, clear, and consistent communication that engages the patient in care.
- 3.** Education about therapy – including correct inhaler technique – and patient motivation are critically important. Patients who are not only knowledgeable about their disease but also motivated and engaged in care are more likely to be adherent and have better health outcomes. Health care professionals may need to pay particular attention to education and training to ensure that the appropriate information is delivered in a way that is understandable to patients.
- 4.** As chronic diseases, asthma and COPD can affect patients in a variety of settings. Pharmacists, family and caregivers, and health systems and employers can contribute to care by reinforcing education, providing support, and providing additional resources and/or training to patients. However, these individuals and organizations may need more knowledge about asthma and COPD and their treatment to be effective in these roles.
- 5.** Pharmaceutical companies and regulatory authorities play an indirect role in care by developing and approving, respectively, patient-friendly devices, use instructions, and training and management tools. Knowledge about patients and attention to use challenges and health literacy issues will enable the pharmaceutical industry and regulatory authorities to better address patients' needs as well.
- 6.** Multidisciplinary dialogue is needed to establish increased mutual understanding and identify practical ways to implement and measure the success of the integrated approach presented in this article.

Critical Communications

People with chronic diseases require consistent, continuous and correct communications from diagnosis throughout the life of the disease. There are very important times where communication may significantly affect adherence.

1. **Time of diagnosis:** Communicating that asthma and COPD are serious but controllable chronic diseases that require life-long management is important and should be reinforced at each appointment. Information may not initially be absorbed or may be quickly forgotten.
2. **Point of care:** Every visit to a health care professional, related or unrelated to asthma or COPD, may be used as an opportunity for education and discussion about patients' needs, goals, and preferences. This includes visits to primary care physicians and clinicians, specialists, respiratory therapists; sports physicals; and emergency care visits. To be effective, communication should be clear and consistent with evidence-based messages; short, simple queries may confirm that everyone has the same understanding. Example questions include:
 - a. At the Diagnostic Visit: "What did you think when I first said you (your child) had COPD (asthma)?"
 - b. At subsequent asthma or COPD visits: "Are you hearing different things about asthma from different people such as the school nurse or the pharmacist or the allergist?"
 - c. To confirm shared understanding after a decision about a new or ongoing medication: "Could you tell me how you will use this medication? For what reasons? How many times a day? I want to make sure we are on the same page."

Suggesting that the patient take notes, allowing opportunities for questions, and confirming that the next appointment is scheduled can reinforce the importance of continued shared care.

3. **Transitions of care:** Transitions in care settings are very common in chronic diseases such as asthma and COPD. These diseases affect people as they move between ambulatory and hospital settings to their homes, places of work, and school. Health professionals are only present for a small fraction of the time that patients face asthma and COPD challenges, so engagement of core and extended care team members and consistent messaging is important to limit confusion and promote

adherence. Patients are experts on their experiences and the information they provide can be used to collaboratively design care for everyday management.

4. **Demonstration may be worth 1,000 words:** It may be difficult for patients to grasp every important step in inhaler use from written or visual instructions alone. Physicians and staff should be able to correctly demonstrate inhaler use and have multiple methods for instruction. Asking patients to demonstrate how they use their inhalers at every visit can help confirm that their technique is correct, and present opportunities for additional education.
5. **Communication is not a monologue:** Time limitations, impatience and stress can make clear, constructive communication challenging. However, unanswered questions may lead to a visit to the ED, an after-hours call or frustration, fear and increased symptom burden. Allowing more than seven seconds before interrupting and welcoming additional questions may prevent an emergency situation, a missed school or work day or reduce poor adherence.

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