What Does It Take to Have a Successful Noninvasive Ventilation Program?

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Introduction

The use of noninvasive ventilation (NIV) has dramatically increased over the last decade. This increase is multifaceted with regard to the number of patients receiving NIV and in the increasingly varied disease conditions for which NIV is being used. Successful development of an NIV program depends on many variables, but perhaps most important is a multidisciplinary approach that incorporates experience and education. Many aspects of an NIV program must come together to make it successful for both patients and clinicians. Among these are needs assessment, institutional buy-in, use of proper equipment, staff and patient training, protocols/guidelines, and outcomes. We analyze these issues and identify characteristics that produce a successful NIV program. Key words: noninvasive ventilation, outcome measurement, intensive care unit, ICU, intermediate care, multidisciplinary, mechanical ventilation, endotracheal intubation. [Respir Care 2009;54(1):53–59. © 2009 Daedalus Enterprises]
tered to deliver aerosolized medication. The focus has shifted in the last decade from medication delivery to ventilatory support, to avoid endotracheal intubation (and its associated risks and complications) and invasive mechanical ventilation. NIV can be an alternative to invasive mechanical ventilation in some cases, but it should not be considered a replacement for invasive mechanical ventilation. A greater understanding of the appropriate indications for NIV, coupled with advances in NIV equipment, will lead to a successful therapeutic application. Currently NIV is used in various forms of acute respiratory failure, and is the standard of care for certain forms of respiratory failure, such as chronic obstructive pulmonary disease and congestive heart failure.

**Needs Assessment**

Prior to initiating an NIV program, an institution must conduct a needs assessment to determine the number of patients who could be eligible for NIV. The needs assessment is necessary to calculate the costs of capital equipment, disposable goods, training, and personnel time required for the NIV program. Although it is not possible to predict exact patient admission data, a retrospective review of patterns will display general trends sufficient to estimate the needed NIV resources.

Development of a successful NIV program then hinges on several factors, beginning with institutional buy-in, followed by training, equipment acquisition, determining the location(s) NIV is to be used, and determining and implementing monitoring capabilities. Outcome measurements are key to determining if the program is successful, and can identify opportunities for improvement.

**Institutional Buy-In**

Merely identifying NIV as a therapeutic option is not sufficient to garner institutional approval and establish an NIV program. Factors that must be considered before implementing an NIV program include literature support, provider agreement, and economic justification.

**Literature Support**

Early use of NIV began emerging after a series of successful anecdotal reports were published. However, without a standard approach to deliver NIV, those early reports of success may not translate to a future therapeutic option without an established continuum of care. A literature review is an important early step, to understand the evolution of NIV, present utilization trends, and the benefits of and possible problems with NIV.

The scientific literature must support the use of NIV in the patient populations that frequent the hospital. There is little value in starting a program if NIV might be inappropriately or infrequently used. A literature search is an important step and relatively easy today with Internet access and the various biomedical literature databases.

One exemplary publication is a survey by Maheshwari et al (Fig. 1) of 82 hospitals in Rhode Island and Massachusetts, which identified the percent of 513 initial mechanical-ventilation starts that were invasive versus noninvasive. 

**Provider Agreement**

All clinicians must be educated on the application of NIV and must agree that NIV is an attractive therapeutic option. Once providers are in agreement, the progress toward institutional approval becomes much smoother. Perhaps the most important factor in implementing a successful NIV program is influencing physician practice. In the current reimbursement climate, clinical practice is directed not only toward patient outcomes but also toward expenditure control. Thus, the key is changing physicians’ ordering practices. Several factors are important for acceptance and promotion of NIV: education, participation in program development, and opportunity to provide feedback. NIV education is essential to connect the NIV procedures to the goals of therapy. The main reason for low NIV utilization appears to be lack of provider knowledge and awareness regarding NIV. Improved knowledge of NIV leads to familiarity, which may foster a more “vested interest” in NIV program development and, ultimately, increased appropriate and efficient use of NIV. Including physicians and other stakeholders in the program-development process enhances the likelihood of success. To complete the circle of communication, feedback, and patient outcome data, all providers should be informed of
Identifying in advance the obstacles to program development will assist the planning team to establish a more focused approach to implementation and training. Figure 2, which is also from the survey by Maheshwari et al.,17 shows the frequencies of the most important reasons for low NIV utilization, as assessed by directors of respiratory care departments. That type of literature helps form a good starting point for the NIV education process. The main reason reported for low use of NIV is lack of physician knowledge, so the bulk of the initial effort should be targeted at NIV education for the physicians. Also identified in the survey were some other issues to monitor: inappropriate NIV equipment, poor previous experience, and inadequately trained respiratory staff. In that scenario, education of physicians, respiratory therapists (RTs), and nurses should be paramount for success.

**Economic Justification**

As with other new initiatives, a financial analysis must be conducted to predict the cost-effectiveness of the NIV program. Respiratory care managers usually have the responsibility for planning, assessing, and budgeting for such programs on behalf of their department and the hospital. The monetary threshold that defines “capital equipment” differs among institutions. The term “capital equipment” applies to mechanical ventilators, extracorporeal life-support systems, clinical information systems, and noninvasive positive-pressure devices.

All capital purchases are initiated from either a perceived need for a new service, for up-to-date technology, for a solution to a problem, or to replace obsolete or worn out equipment. The first duty of the respiratory care manager is to determine the need for and possible benefits from the expenditure of capital dollars for the project. The respiratory care manager, in conjunction with hospital administration, the capital equipment committee, and the finance department, must all work cooperatively to determine the need for the purchase, the alternatives, and the impact of not making the purchase. To provide an appropriately detailed justification, the manager must know the type of and extent of analysis required.

**Program Requirements**

**Equipment for NIV**

NIV equipment selection hinges on 2 main variables. The first is the patient interface. Nasal, oronasal, and full-face masks are all readily available. The choice of headgear to secure the interface also warrants consideration. Headgear that is relatively easy to apply and comfortable is desirable.

The second variable is ventilator type. NIV can be delivered by a blower-based, portable, bi-level ventilator derived from a home-based continuous-positive-airway-pressure system, or by a critical-care ventilator designed to deliver invasive ventilation. Portable pressure ventilators generally function well in less severely ill patients. Newer-generation critical-care ventilators have NIV modes with leak compensation. These ventilators also have more ventilation modes and comprehensive monitoring and alarm capabilities. Patient-ventilator synchrony is an important aspect of NIV, and the newer-generation critical-care ventilators are very sensitive and responsive to the patient’s inspiratory demands.

Ultimately, the severity of illness dictates location and, most likely, which ventilator type is most appropriate. Take, for instance, a patient with chronic obstructive pulmonary disease who presents to the emergency department in much distress, and NIV is instituted. The patient may need to travel for a diagnostic study and may need to be intubated at some point. In that scenario one would ideally want a critical-care ventilator that is equipped for patient transport. That way you have a ventilator that is very responsive to the patient’s ventilatory needs and that can ventilate effectively if the patient requires intubation.

Other NIV equipment issues include cost and frequency of use. If NIV will be used mainly in a step-down environment, then a standalone unit is more appropriate from a cost perspective. However, an institution with a large and active emergency department may require a mixture of standalone positive-pressure ventilators and critical care ventilators capable of delivering NIV.
Leadership and Personnel

For institutional approval, a multidisciplinary development group should be established initially. This group should consist of stakeholders who represent physicians, respiratory care, and nursing. That group’s job is to identify the specific need for NIV and the locations where it will be used. They will need to assess potential barriers and strategies to overcome them, and then to develop an implementation plan and an outcome-reporting plan for feedback and reinforcement. The program should be flexible so that adjustments can be made based on institutional outcomes and published research. The planning group should develop a communication pathway to keep all members of the health-care team informed. Some clinicians on staff may have NIV experience from work at other institutions, and these people are a valuable resource, especially for identifying and overcoming potential barriers and problems.

Several factors must be considered in justifying an NIV program. How does the request fit with the hospital’s long range plan? How will the project impact other services in the hospital, the department, other clinical departments, and support services? How will the program affect duration of stay and quality of care? Does the medical staff support the project? What is the effect on staffing? What training will be required? Overlooking any of these questions may cause problems in the process.

In all likelihood a detailed financial justification for an NIV program will be required. The amount of detail will depend on the complexity and the size of the program. Collecting detailed financial data is necessary to determine the total cost of the program and the amount that will be allocated each year throughout the life of the equipment. The point of this analysis is to determine the financial payoff of the investment. In and of itself, the financial analysis doesn’t consider issues such as patient safety and improved patient care. It can provide only one piece of the puzzle that must be completed to obtain the entire picture.

The possibility of increased clinician time with NIV is an important consideration. A successful program should not adversely affect clinician time to the point that other procedures would be delayed or not done, or require extra staff. In addition to the cost of capital and disposable equipment, implementing an NIV program will almost certainly increase the respiratory care work load and affect staffing. The staff productivity in relative value units has to be adjusted to accommodate this increased work volume.

An early study indicated that NIV may substantially impact clinician time, but that study was a case series with no control group. Also, it took place early in the history of NIV and the study facility in Switzerland had no respiratory therapy staff. The same group followed up that initial study with a second report that had more encouraging results, most likely due to the learning curve and technological advances. Other later intensive-care-unit (ICU) studies found that there may be a substantial time commitment in the initial startup of NIV. Other studies reported that the time-commitment difference from conventional ventilation drops off substantially after the first 8 hours or so, or is very small over the duration of a patient’s stay. The clinician time commitment probably depends on the level of experience with NIV. Any additional clinician time involved in NIV startup is certainly now due to patient coaching and education. When a patient is intubated and placed on a mechanical ventilator, there is very little or no coaching and education. NIV is constantly being refined and streamlined, so the main limiting factor now is not the equipment but the staff training and experience.

Training

Training in NIV, similar to all other modalities of positive-pressure ventilation, must be thorough and documented. It also needs to be flexible enough to apply to RTs, physicians, nurses, and other clinicians. The physician training centers on identifying appropriate patients and understanding the goals and risks of NIV. Nurses need an understanding of mask placement, alarm interpretation, patient assessment, and potential results, based on patient condition. The training requirements, even among RTs, depend on the clinician’s experience. If the department is setting up this service de novo, then the training requirements may be quite demanding initially. However, if a sufficient portion of the staff and/or supervisors have substantial NIV experience, the implementation process could be much smoother. In the latter scenario, preceptor-based training may be the best way to proceed.

RT NIV training should include the rationale for the therapy, mask and headgear fitting techniques (coaching), ventilator circuit assembly, theory of operation, ventilator adjustment, equipment maintenance, and problem-solving and troubleshooting. Using a critical-care ventilator to deliver NIV can increase the difficulty of NIV training because critical-care ventilators have numerous settings, monitoring capabilities, and alarms.

In a survey, Burns et al found that physicians learned about NIV mainly from other physicians, RTs, and hospital education programs. Fewer than half the respondents obtained information from conferences, original research articles, systematic review, or the Internet. Ongoing education is also vital and should be based on need (after identification of a technique not consistently being properly performed), outcomes, and emerging trends in the literature. The ongoing education should apply to all members of the health-care team. Ongoing education is especially important in acute-care centers because of an-
nual resident physician turnover. Formal education sessions may also not be practical because of time commitments. Offering the option of NIV during patient-care rounds can be a valuable opportunity for physician training.

Schettino et al did a prospective observational study of all their patients who received NIV, to compare their practice to that of the published randomized controlled trials. Their results were similar to prior literature, and their success was attributed to the training of the respiratory care staff and the orientation of the nursing staff.23 The respiratory care education consisted of a 4-hour training session in which indications, equipment, and techniques were discussed and demonstrated. All nursing personnel received classroom orientation and bedside instruction from the RT while applying NIV to the patient.23 The frequency of ongoing education sessions for RTs and physicians should be based on the frequency of use. Emphasis should be on patient selection, initial pressure settings, monitoring, subsequent adjustments based on clinical status and gas exchange, and criteria for endotracheal intubation.

Protocols: Guidelines for Delivery

Choice of ventilation mode can be based on expertise and familiarity, but ideally a protocol would standardize and educate clinicians on the best way to proceed. The protocol should then be tailored to the etiology and severity of the respiratory failure. A word of caution about the use of a protocol: it shouldn’t take the place of clinical judgment.

Implementing a specific NIV protocol could help facilitate therapy standardization and help identify appropriate patients. Important considerations concerning protocol implementation include interactive education, timely and specific feedback, physician participation, administration interventions, and adequate staffing. The most important aspects of implementing an NIV protocol relate to its initiation and the recognition of its successes and failures.

Another avenue to both successfully implementing an NIV program and enhancing clinician education is the clinical practice guideline.24 Development of a clinical practice guideline involves a multidisciplinary approach with structured education sessions for all clinicians involved. Rigorous education is required for guideline adherence, so this type of vehicle is a valuable educational tool.

Experience is probably the most important factor in treating severely ill patients with NIV. Carlucci et al found that, over an 8 year period, established practice with NIV allowed for treating more severely ill patients with the same success rate.25 With all other factors (number of staff, equipment, environment) remaining constant, Carlucci et al attributed that success with NIV to increased familiarity and progressive training.25

Location and Monitoring

The likelihood of NIV success is important in determining where the procedure should be performed. Factors that influence NIV location include staff experience and training, RT availability, and access to intubation.26,27 The most important factor is clinician experience.26 While training is also important, it is not a substitute for experience. The decision on where to use NIV also will depend on available respiratory equipment and monitoring capabilities.

An ideal place for NIV would seem to be the emergency department.4,10,13,28-37 Bott et al, in an early randomized study with 60 patients, found NIV success in dyspnea-relief and outcomes in the emergency department and ward.13 However 2 studies from the 1990s found that NIV had no advantage over conventional therapy.27,29 It is noteworthy that in the study by Wood et al the worse outcomes in the NIV group were partly attributed to delay of intubation.27 It would make sense, though, that if early use of NIV in the emergency department prevented intubation and/or admission to the ICU, then NIV would be valuable.

Potential benefits of NIV outside the ICU include early intervention to prevent further respiratory deterioration, and respiratory support in a less intimidating environment. Plant and colleagues studied 236 patients with chronic obstructive pulmonary disease admitted to the general respiratory ward for respiratory failure. The patients on NIV required intubation less often and had lower in-hospital mortality.12

A study by Paus-Jenssen et al illustrated how NIV can be successful outside the ICU.30 In a tertiary-care center in Saskatoon, Saskatchewan, Canada, 81 patients placed on NIV were prospectively followed. NIV was started (n = 75) most often in the emergency department (32%), then in critical care (27%), the observation ward (23), and the general ward (18%). The decision and location for a patient to be placed on NIV were physician-dependent. The physicians (n = 75) who ordered NIV were internists (35%), intensivists (20%), casualty officers (12%), surgeons (12%), cardiologists (12%), pulmonologists (5%), and anesthesiologists (4%).

NIV outside the ICU is an attractive option, given the considerable pressure for ICU beds; cost of ICU care; and, for families, a less distressful option than the ICU environment. If NIV is started outside the ICU, several factors have to be taken into account. Once again, staff education and availability are key elements for success. Another important aspect is the monitoring capabilities of the specific location. A general ward has fewer monitoring capabilities than an ICU, and intermediate-care units have moderate monitoring capabilities. Important variables when following a patient on NIV include arterial blood gas values, vital signs, patient comfort, mental status, mask leaks, and the patient’s ability to expectorate secretions. The monitoring
level should be determined by the severity of the patient’s condition and the site of care. Once NIV is initiated, careful assessment is vital. Generally speaking, improvements in level of consciousness, pH, and $P_{\text{aCO}_2}$ within the first hour are associated with NIV success.\textsuperscript{31}

**Assessing Outcomes**

From an economic perspective both inside and outside the ICU, NIV is attractive for patients who would otherwise be intubated, which is associated with high costs.\textsuperscript{26} Economic analysis in the medical arena is very complex because of the multitude of personnel, diagnostic tests, and therapeutic technologies involved. Steps in economic analysis include calculating the cost of the interventions and evaluating the outcomes. The first step is to determine the cost of the NIV program’s equipment, supplies, capital, overhead, medical personnel, laboratory tests, pharmacy costs, nutrition, and ventilation. The second step is to evaluate outcomes, which can be analyzed in terms of economic resources saved or created, and efficacy in terms of intubation and survival.

NIV shortens ICU and hospital stay,\textsuperscript{3,10,11,32-34} and thus decreases costs, compared to the previously used standard therapy. NIV reduces mortality by avoiding complications associated with intubation and by shortening the duration of mechanical ventilation.\textsuperscript{10,32,35} In 2007, Antonelli found that NIV can be effective in a subset of patients with acute respiratory distress syndrome.\textsuperscript{36} That finding may reduce costs, because patients with acute respiratory distress syndrome typically require longer ventilation and more hospital days than patients with acute respiratory failure.

Keenan et al performed a meta-analysis of the available randomized trials and concluded that NIV was more effective than standard therapy in reducing hospital mortality. Additionally, NIV was associated with a cost savings of approximately $2,500.\textsuperscript{15} Another report found that the daily costs associated with a ventilated patient could be reduced by 66% if care were performed in a specialized respiratory unit, as opposed to an ICU.\textsuperscript{37} Although that finding seems promising, extrapolation of that finding to the assumption that costs associated with ventilation could be reduced even further if it were carried out on the general ward should be taken with caution. The effectiveness of NIV could be hampered because the wards do not have the same clinician/patient ratio as the ICU, and the ward clinicians may have less NIV experience than the ICU clinicians. Ultimately, NIV may decrease ICU resource utilization, or it could have the opposite effect, of increasing costs due to training and education if there is a substantial initial learning curve.

Outcome measurements could also include mortality, percentage of patients who undergo intubation after initiation of NIV, location of NIV patients, and order appropriateness. A feedback-collection system that captures the patterns of use and outcome measurements is invaluable for improving the institutional NIV practice.

**Summary**

A multidisciplinary approach is imperative for NIV program success. Protocols and clinical practice guidelines are invaluable as educational and practice-standardization tools. Clinician availability and patient/clinician ratio are also important factors when evaluating the impact of an NIV program. For a patient with severely impaired gas exchange, NIV should be carried out in a specialized unit so the staff with the most NIV experience is involved and intubation can be performed without delay, if required. Appropriate monitoring needs to be available to the clinicians to round out excellence in patient and therapy assessment. Ultimately, a step-by-step clinical protocol that incorporates frequent assessment is ideal for NIV. The protocol should be based on the latest research, but it should not be a substitute for ongoing education and training.

**REFERENCES**

Discussion

Gay: I appreciated your showing Sean Caples’s protocol from the Mayo Clinic.1 When we put that together, we found 2 barriers that were most prominent when we were trying to enact some sense to the protocol of what was going on in the institution. The top box addresses the goals. Some people have a very knee-jerk response for the initiation of NIV just for respiratory distress, and they don’t ask the appropriate questions up front, such as what are you going to do if NIV fails, and what are your targets?

We spend so much time and focus on acute implementation of NIV. Our experience at the Massachusetts General Hospital. Crit Care Med 2008;36(2):441-447.


always successful, because you’re grinding them out to get that bed free—but we now use what we affectionately call the “10 torr rule.” Before, if the patient was able to come off the mask in the morning (because they typically are admitted in the evening with hypercapnic respiratory failure), and was on oxygen and talking to you in the morning, that was usually the extent of the assessment. But now we keep the patient for 4 to 6 hours after he comes off of NIV, and obtain another blood-gas analysis to see if academia develops; if $P_{CO_2}$ rises by more than 10 mm Hg (“torr”), it’s a pretty good rule that NIV will be needed that night. It doesn’t necessarily mean the patient stays in the ICU, but it gives direction to the people who pick up the patient’s care.

Gay: We do not. It becomes so abused by the house staff, that virtually anybody with respiratory distress gets NIV, and it’s swallowed up our RT workload and other resources.

Kacmarek: Then how do you manage the volume of patients who might benefit from NIV, if they all have to occupy an ICU bed?

Gay: There’s a step-down area as well; I shouldn’t say just the ICU. The point is that we try to make people recognize that this is not a trivial procedure—that the acute distress events we’re using it for require monitoring. NIV initiation that’s crucial is done by the best RTs, with the understanding of why we’re doing this and what our goals are. In the long run, counting anything from ICU bounce-backs to excessive utilization of ICU beds, I think our preference to start it in a more heavily monitored environment has reduced over-use and misuse without undue sacrifice of needed use.

Benditt: It is important that the patient on the floor be able to maintain himself, whether you say one hour or two, or whatever: they have to be able to do that. I see a lot of neuromuscular patients, and we say that they have to be able to take the mask off. We have not had people vomit from gastric distention, but if a patient was unable to get the mask off, it could be a catastrophe. So our neuromuscular patients who require 24-hour-a-day ventilatory support have to be in a monitored setting.

Kacmarek: OK, that’s a fairly compelling number, and similar to where we are, but how do you get all of those patients into the ICU? We have that same number of ICU beds, and clearly we could not accommodate every one of our noninvasively ventilated patients in an ICU.

Davies: To more effectively transfer patients who still require NIV support, we instituted daily assessment, and we emphasize that this is not a trivial procedure. This has helped us immensely, by keeping more NIV pa-
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Attending all team members.

MENT an NIV program, you have to implement problems. If you’re going to implement NIV, you need RT champions to get the other RTs on board. If you have resistance from the RTs or nurses, you’re dead in the water. Everybody’s got to be on board and having favorable experiences. We have tried is empower the RTs as much as possible. We created a physician order sheet with the collaboration of our RTs. The physician writes the order and the RTs go from there, selecting the mask, pressures, and ventilator adjustments.

Cathy Sangeeta that, at least in North America, RTs have the key role in implementing NIV. We also try to identify “champions” among physicians and RTs. You need a physician champion or it doesn’t get ordered, and you need RT champions to get the other RTs on board. If you have resistance from the RTs or nurses, you’re dead in the water. Everybody’s got to be on board and having favorable experiences. We have tried is empower the RTs as much as possible. We created a physician order sheet with the collaboration of our RTs. The physician writes the order and the RTs go from there, selecting the mask, pressures, and ventilator adjustments.

Davies: The protocol reduced the resistance from nursing staff. I believe they are more comfortable with a specific delineation of responsibilities. The physician orders NIV via protocol, and the RTs carry out the therapy. This works well in our institution, though I do have concerns about the residents’ level of involvement. In many instances, once the order is written, physicians only hear sporadic progress reports, and they become removed from the therapeutic steps taken per the protocol. In many instances these same residents leave for smaller hospitals that don’t have NIV protocols and they become attending physicians and may not have had enough NIV experience and training to outline the most appropriate outcome plan. From a physician’s perspective, protocols are great if the physician is staying in the larger institutions where NIV protocols are more prevalent. However, physician training is imperative in the event that they move into practice in more remote areas.

Hill: John, I really appreciated hearing this from an RT’s perspective, because I often hear it from the physician’s perspective. I agree with Sangeeta that, at least in North America, RTs have the key role in implementing NIV. But some countries don’t have RTs. We all know that NIV is a team effort, and you need physicians to select appropriate patients, RTs to implement the therapy, and nurses to monitor it and alert the RT to problems. If you’re going to implement an NIV program, you have to attend to all team members.

We’ve been working on this kind of approach with our NIV project in Massachusetts, where we’re trying to direct education efforts at all 3 groups, including emergency-department physicians. We also try to identify “champions” among physicians and RTs. You have a physician champion or it doesn’t get ordered, and you need RT champions to get the other RTs on board. If you have resistance from the RTs or nurses, you’re dead in the water. Everybody’s got to be on board and having favorable experiences. We have tried is empower the RTs as much as possible. We created a physician order sheet with the collaboration of our RTs. The physician writes the order and the RTs go from there, selecting the mask, pressures, and ventilator adjustments.

Kallet: I’d like to comment about where you utilize NIV. I think this discussion has to be put within the context of the institution. You have a place like Massachusetts General Hospital, where, with the way it’s set up, it may be very appropriate to have NIV done on the floor. In stark contrast, I work at a county hospital with very limited resources and staffing on the general wards. If you can’t tightly control your NIV program, there is a real danger of clinicians using NIV out on the wards in an unsafe environment. It’s a set-up for a “perfect storm.” Inevitably there’ll be a situation when beds get real tight and some patient on NIV ends up in an unmonitored back room. His mental status diminishes, he vomits into a mask, and it goes undetected.

Having run protocols for a number of years, I can see how very quickly RTs and staff run away with it. I think that when you start a program, if you start it in the ICU or a step-down unit, you should have strict rules about where you place patients on the general ward. You don’t want to start a program and very quickly end up with a “sentinel event” that could squash the program.

Epstein: Most of us have NIV protocols in our institutions. Should those be evidence-based? I sense that there’s a lot of “homegrown” protocols that have never been tested to make sure they are the maximally effective.

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