

Development of a minimization instrument for allocation of a hospital-level performance improvement intervention to reduce waiting times in Ontario Emergency Departments.

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ABSTRACT

Background: Rigorous evaluation of an intervention requires that its allocation be unbiased with respect to confounders; this is especially difficult in complex, system wide health care interventions. We ~~report the developed~~ ed ment of a short survey instrument to identify factors ~~to be used as part of infor~~ a minimization algorithm for the allocation of a hospital-level intervention to reduce Emergency Department (ED) waiting times in Ontario, Canada.

Methods: Potential confounders influencing the intervention's success were ~~first~~ identified by literature review, and grouped by healthcare setting specific change stages. An international multi-disciplinary (clinical, administrative, decision-maker, management) panel ~~examined-evaluated~~ these factors in a two-stage survey-modified-Delphi and consensus discussion nominal group process. ~~The panel's evaluation was~~ based on 4 domains: change readiness, evidence base, face validity, and clarity of definition.

Results: An original set of 33 factors were identified from the literature. The panel reduced the list to 12 in the first round survey. In the second survey, experts scored each factor according to the 4 domains; summary scores and consensus discussion resulted in the final selection and measurement of 4 hospital-level factors to be used in the minimization algorithm: improved patient flow as a hospital's leadership priority; physicians' receptiveness to organizational change; efficiency of bed management; and physician incentives supporting the change goal.

Conclusions: We developed a simple tool designed to gather data from senior hospital administrators on factors likely to affect the success of a hospital patient flow

improvement intervention. A minimization algorithm will ensure balanced allocation of the intervention with respect to these factors in study hospitals.

Key Words: health intervention, emergency department, readiness for change,

Document: Abstract: 250 words; Text: 2524 words; Tables: 3; References: 44.

INTRODUCTION

Balancing Potential Confounders in Evaluation of Hospital-level Interventions

Rigorous evaluation of an intervention requires that its allocation be unbiased with respect to confounders. Randomization provides a mechanism for ~~assuring the expectation~~ensuring that intervention and control groups are balanced in terms of both measured and unmeasured confounders. However, if the sample size for the intervention is small there still may be substantial imbalance in the distribution of key confounders due to random error. One way to help circumvent this problem is to stratify or match on key characteristics before randomization. In order for this to work a small but inclusive set of key potential confounders must be identified.

This paper describes a modified-Delphi and nominal group process that resulted in the development of a short survey instrument that defines potential confounding factors likely to influence the success of a ~~specific system-wide~~ hospital-level intervention to reduce emergency department length-of-stay. The purpose of the instrument is to guide the dynamic randomization of participating hospitals to the intervention ~~program~~, using the method of minimization, ~~as the means to rigorously evaluate the impact of the program~~. Dynamic randomization, enabled by the method of minimization is a widely accepted randomization approach in clinical and multi-institutional trials [1-5]. The minimization method begins with the determination of a small number of factors, ~~usually dichotomous in measurement or categorization~~, known or believed to confound the effect of the intervention. The method assigns subjects to a balanced allocation sequence or to

treatment groups with respect to marginal frequencies between these selected covariates. This is achieved by an algorithm which allocates the intervention to each subject, in our case, a hospital, that volunteers and is eligible to receive the intervention [6-8].

Overview of the Intervention Being Evaluated

Every year in Canada more than 12 million Emergency Department (ED) visits are made,[9] and about a quarter of Canadians visit an ED for themselves or a close family member.[10] Recently, prolonged waiting times in EDs have been the subject of much debate in Canada and elsewhere, and several jurisdictions have launched interventions to reduce them. In 2008, the Ontario Ministry of Health (MOH) announced a provincial ED ‘wait times strategy’ designed to improve ED patient wait times, patient flow and patient satisfaction. The strategy includes an ‘Emergency Department Process Improvement Program’ (ED-PIP), a hospital-level intervention intended to improve hospital processes for admitted ED patients in order to improve access to in-patient beds and reduce ED waiting times [11-15].

The intervention will be implemented over three years in approximately 90 acute care Ontario hospitals with high-volume emergency departments (those receiving > 20,000 patient visits/annum). It will focus on organizational changes in three areas: i) more efficient processes (reforming/ standardizing policies and practices); ii) greater engagement of frontline staff in problem-solving; and iii) supportive management systems. Modeled after three Ontario demonstration projects [16], the intervention is supported by a leadership and training program and organizational change experts in the

form of coaching and training teams who facilitate the program in collaboration with local leaders and staff teams from participating hospitals. Change experts and hospital teams are tasked to improve processes from patient presentation in the ED to in-patient admission through to discharge by the integration of performance improvement pilot solutions across the ED and General Medicine Units.

In collaboration with senior decision makers at the Ontario MOH, a roll-out and evaluation strategy for the intervention was developed. The primary objective of the evaluation of the intervention is to determine whether the ED-PIP ~~improves~~ reduces total Emergency Department length-of-stay (ED-LOS). The secondary objectives are to determine the effects on time-to first physician contact and several measures of quality of care.

METHODS

We conducted a literature review ~~t~~To identify a list of possible minimization factors to guide the allocation of hospitals to the ED-PIP ~~we conducted a literature review.~~ Subsequently, a multi-stage modified-Delphi ~~structured~~ expert panel process was performed that included candidate factor review, quantitative assessment and a nominal group process in a final teleconference discussion.

Literature review: To generate the list of candidate minimization factors we reviewed databases from Management and Organizational Studies, PubMed/Medline and Ovid HealthSTAR using the search terms: organizational culture, healthcare / health

system reform, transformation, intervention(s), context, evaluation, readiness for change, change management, implementation, process and outcomes. We sought to identify articles and research papers specifically focused on organizational change and behaviour, change interventions and research reports specific to healthcare and health services administration. One author (CL) examined all relevant references; candidate factors were considered regardless of any demonstrated empirical association to outcomes of the policy intervention under study.

The literature review [17-26] generated a preliminary list of potential factors associated with the success of organizational change interventions in healthcare settings. These, which were organized according to a published 4-stage framework for healthcare professionals managing organizational change [20]. This framework builds on observational studies in change management literature and provides a model of change implementation in healthcare organizations, informed by the implementation of a major patient safety initiative at a large, multi-site, academic hospital in Toronto, Canada.

Candidate factors were retained if they were relevant to the first 3 stages in the framework, which represent the most applicable domains of organizational capacity and readiness for change relevant to the implementation success of the ED-PIP. The last stage addresses long-term sustainability of change initiatives. Given the breadth of indicators relevant to change stage 2, we expanded this stage into two subcategories: a) organizational readiness for change; and b) situational analysis and redesign of organizational systems.

Expert panel: We assembled an international multi-disciplinary panel of 21 experts consisting of hospital and Emergency Department administrators, physicians and nurse clinicians, health services and policy researchers, Ministry of Health senior leaders, organizational change researchers, and consultants with extensive experience in hospital change management interventions. Panelists represented health systems in Canada, the United Kingdom, and Australia. Diversity of experience from teaching and non-teaching hospitals was well represented among panelists. Consultants identified by two co-authors (RB, BG) were contacted and asked to nominate global experts who 1) had experience facilitating organizational change management in health sectors abroad; and 2) were familiar with the proposed intervention concept.

Structured Panel Process/Modified-Delphi and Nominal Group Process

In a preliminary stage, panelists reviewed the list of factors generated from the literature review and were asked to suggest additional factors based on their knowledge of the literature and experience with health system improvement initiatives. A final list of candidate factors was generated and a two-round [modified-Delphi](#) survey process followed. In round 1, panelists rated candidate factors with respect to their [probable/expected](#) correlation ([High, Low, or Unsure](#)) with the allocation strata for the intervention (Hospital volume ~~:-high, medium;~~ and geographic region). [Previous research in Ontario suggests that variation in ED-LOS is based on ED-volume and the geographic region of a given hospital\[27\].](#) [Factors that were Highly correlated factors werewith stratification variables were](#) excluded since [any](#) confounding associated with them would be [assumed to be](#) dealt with through stratification. Panelists also rated the

degree to which the factor would likely confound the effect of the ED-PIP on achieving improvements in ED-LOS and in-patient flow. Those rated as ‘somewhat’ and ‘very’ were coded as ‘Predictive – potential confounder’, those rated as ‘slightly’ and ‘not at all’ were coded as ‘Not predictive – not a potential confounder’. Factors rated by greater than 70% of panelists as ‘Predictive – potential confounder’ were retained for the second survey.

In order to obtain a broader perspective on potential confounders, we expanded the number of participants for the second survey [28,29]. In this phase, panelists rated each of the factors retained previously on a scale of 1 to 9, where 1 was ‘completely disagree’ and 9 was ‘completely agree’ for the following three questions:

- a) The factor measures a core component of a hospital’s readiness to implement and facilitate an organizational change policy intervention aimed to improve ED-LOS and in-patient flow through to discharge;
- b) The factor is highly predictive of the capacity for an organization to successfully implement the intervention and achieve improvements in patient flow; and
- c) The factor is evidence-based and linked to a hospital’s ability to manage change activities related to the patient flow intervention.

~~The factors were grouped according to each change stage domain and~~ a final score for each factor was derived by averaging the responses from the 3 questions noted above $(a+b+c/3)$. Results were reviewed by panelists and discussed [among the core group of panelists](#) via teleconference [guided by the nominal group technique](#). The highest ranking factor for each change stage domain was brought forward for discussion, definition and specification of a measurement scale. [The resulting minimization instrument was pilot tested using a web-based survey to Chief Executive Officers from 6 hospitals chosen to pilot the ED-PIP intervention](#). Hospitals were selected by the Ministry of Health. [We categorized responses from 1-9 as: Lowest \(1-3\); Moderately-Low \(4-5\); Moderately-High \(6-7\); and Highest \(8-9\)](#). This study was approved by the Sunnybrook Health Sciences Centre Research Ethics Board (ref#324-2007).

RESULTS

A total of 33 candidate minimization factors were generated from a literature review and initial consultation with panelists [\(See Appendix 1\)](#). Candidate factors related to the implementation of the ED-PIP and covered a broad spectrum of issues (see Table 1; [or Appendix 1](#)).

The first round questionnaire was circulated to the core group of panelists (n=19); 11 (59%) panelists completed it. Twelve of the original 33 (36%) factors were retained for the second survey. The second round questionnaire was distributed to 21 panelists, [\(original 19, plus 2 international representatives\)](#) and 17 (80%) panelists completed it. Table 2 lists the second round questionnaire results for all 12 indicators emerging from

the original 33. For each change stage, ~~the~~ top ranking ~~measures-factors~~ across the domains were discussed; ~~the factors, and the variable with~~ with the highest average score ~~in each domain was confirmed in the discussion as the was selected by~~ consensus choice ~~as the factor~~ to include in the minimization algorithm. Panelist discussion via teleconference using the nominal group technique served to -further clarify ~~ied~~ factor definition, appropriate wording, and response scale (1-9) for the short survey instrument. The final four minimization factors are listed in Table 3.

A total of 6 CEOs from a selected sample of ED-PIP hospitals received an invitation to complete the online survey and all (100%) completed it. The distribution of respondent scores across levels from Highest to Lowest was: 4,0,1,1 for factor 1; 1,3,2,0 for factor 2; 0,5,1,0 for factor 3; and 0,2,2,2 for factor 4.

DISCUSSION

Using a combined approach of evidence synthesis and a modified-Delphi panel and nominal group process we identified 4-factors to be used in ~~structured expert panel review process, we developed~~ a minimization algorithm ~~based on 4 factors~~ to guide the allocation of hospitals to the ED-PIP intervention. This structured panel process reduced 33 initial candidate factors to 4, expressed as a simple four-item quantitative survey instrument. To our knowledge, this is the first published example of a minimization algorithm being used to allocate hospitals to a major health system policy intervention.

The intervention being developed to improve patient flow is complex, and complex interventions generally demonstrate modest gains in empirical study [30]. Evaluating

such interventions requires careful balance of known and unknown confounders, since the effect of confounders may exceed the effect of the intervention, in either direction, to create a benefit which is not real or hide a benefit which is real. This is an important advantage of randomized studies (and one which policymakers are generally not aware of), and pragmatic randomized trials of complex interventions can be designed so that they are no more difficult for policy-makers to implement and evaluative rigor is ensured. This can be especially important when the number of intervention units is small, say less than a hundred hospitals, rather than a few hundred thousand patients as is more typical in patient-level intervention studies.

The disadvantages of randomized trials in the health care system includes their cost, complexity and the desire for rapid changes evidenced within political mandates (randomized controlled trials take considerable time). Due to these issues, decision-makers often implement non-randomized observational designs (e.g., before-after), which are vulnerable to confounding and offer relative uncertainty with regard to understanding the true impact of transformative efforts to improve system performance, accountability and quality of care to the consumer. Methods such as matching or stratifying by factors such as geography, hospital type, or volume are appropriate means to balance some confounders, but there is a limit to the number of strata one may use; minimization offers an alternative or complementary approach to ensure allocation is balanced with respect to important confounders of the ED-PIP intervention.

The minimization algorithm aims to ensure unbiased allocation of the intervention during its phased roll-out. Each factor has been defined in the form of a question with a 9-level response scale. Responses from volunteering hospitals will be assessed for variance and grouped into two levels (0 'Low' and 1 'Moderate/High') accordingly for evaluation in the minimization algorithm. The algorithm allocates the first hospital in presenting sequence of eligibility to receive the intervention in the first (Year 1) or later phases of implementation at random. The algorithm then allocates subsequent hospitals to each respective phase of the intervention minimizing differences across factor levels, such that, in each phase of implementation the sample is balanced with respect to hospitals with both low and moderate/high levels of each factor. In our pilot testing, we observed substantial variability between the 6 respondents on three of the four factors, suggesting that our minimization factors do discriminate and are suitable for use in the minimization algorithm to guide the allocation of the intervention to hospitals. All respondents rated factor 3 (effectiveness of bed-management) as 'Moderately high'; it will therefore be important to monitor the variability in this factor when the survey is completed by CEOs from additional hospitals in Ontario as the ED-PIP is rolled out. Further pilot testing in additional hospitals is likely required before this tool can be widely recommended.

The organizational change management literature contains a large number of potential factors or mechanisms likely to represent either a barrier or facilitator to achieving change [17,19,20,23,31-39]. These are largely based on retrospective cross-sectional observation and evaluation of change interventions [40]. There are few longitudinal [41] studies or rigorous evaluations of these factors [42]. Gustafson and colleagues [39],

however, offer a concise review of potential factors; and illustrate and test an 18 factor model devised to predict and explain the success or failure of a change process in healthcare settings. The model was derived from expert panel review and literature consult, but was neither evaluated with respect to objective outcomes nor designed to be used for intervention allocation purposes. Rather, the factors were compiled to guide managers initiating and managing a change initiative within a health care setting on actionable determinants of implementation success. The model is too complex for allocation using a minimization algorithm due to the number of factors and levels within each. Further, most factors are concerned with optimal intervention design and implementation rather than organizational culture or context factors likely to confound intervention success/failure. Our four factors are not designed as a comprehensive list of all potential factors affecting success of a hospital level policy intervention, but rather as important hospital-specific factors likely to confound success/failure of the intervention at all phases of implementation.

Some study limitations are worth noting with respect to our process to define potential determinants to implementation success of the ED-PIP. While our literature review was comprehensive, it was confined to English peer-reviewed publications and may not have identified all possible previously cited factors. ~~Moreover, time did not permit a comprehensive review of the gray, non-English and unpublished literature.~~ Our consultation with the panel of experts, however, did yield additional factors in the preliminary exercise, ~~so we feel the bias here is small.~~ The minimization factors were developed with specific reference to the ED-PIP intervention; therefore, the 4 factors we

identified may not necessarily be relevant for other hospital-level interventions. However, many of the obstacles to organizational change in healthcare settings potentially affecting success of a patient flow initiative are likely common to other interventions as well. Indeed, our factors are similar to previously cited themes of obstacles to implementation success described in organizational change research within and beyond the health sector [18,19,22,26,31,37-39,43]. [While our pilot results suggest reasonable variability across the four factors, we suggest caution to researchers who may wish to use these factors in other settings; piloting the instrument in a small number of centres prior to allocation based on these minimization factors is advisable.](#)

[Lastly,](#) the international membership of our panel made an in-person meeting prohibitively costly; however, regular electronic contact was maintained and timely feedback occurred. Biases may have resulted during the in-person / teleconference panel meeting from single panelists whose opinion may have been overly influential; however, the teleconference method may have mitigated this, and input was actively sought from all attendees.

CONCLUSIONS

Change in all industries is difficult, perhaps in none more so than health care, where multiple stakeholders, sometimes conflicting missions and goals, professional independence of key staff, and difficulty accessing high quality performance data present particular challenges [20]. Policies and interventions to improve hospital performance frequently require significant human and financial resource inputs, and rigorous

evaluation is necessary both to evaluate their effectiveness and to better understand organizational factors contributing to success [44,45]. The evaluative strategy for the ED-PIP ensures that the intervention can be implemented in a way that is consistent with the needs of policy and health system decision makers, while at the same time offering a study design that provides for a rigorous evaluation of its effect on patient LOS in the Emergency Department.

Declaration of competing interests

The author(s) declare that they have no competing interests.

Author's Contributions

MS, AG, MZ, GA, ST, GB, BR, MD and AH conceived of the study and design to systematically identify minimization factors, participated in the expert panel review process; and helped to draft the manuscript. CL carried out the literature review, coordinated and synthesized results from the panelist surveys; and drafted the manuscript. MS facilitated the teleconference. All authors read and approved the final manuscript.

Acknowledgements

We appreciate all those who contributed to the development of the study design and evaluation of the candidate minimization measures, including the core investigator group:

Michael Schull, MD, MSc; Senior Scientist, Institute for Clinical and Evaluative Sciences; Director, Division of Emergency Medicine, University of Toronto; and Associate Professor, Department of Medicine, University of Toronto, Staff, Division of Emergency Medicine, Sunnybrook Health Sciences Centre, Toronto, ON.

Robert Bell, MDCM, MSc; President and Chief Executive Officer, University Health Network, Toronto, ON.

Geoff Anderson, MD, PhD; Senior Scientist, Institute for Clinical and Evaluative Sciences; Professor and Chair, Health Management Strategies Department of Health Policy, Management and Evaluation, University of Toronto, Toronto, ON.

Merrick Zwarenstein, PhD; Director, Health Services Sciences, Sunnybrook Research Institute; Senior Scientist, ICES; Associate Professor, Health Policy Management and Evaluation, University of Toronto, Toronto, ON.

Therese Stukel, PhD; Senior Scientist, Institute for Clinical and Evaluative Sciences; Adjunct Professor of Health Policy, Management and Evaluation; and Associate Member, School of Graduate Studies, at the University of Toronto, Toronto, ON; and Adjunct Professor in the Dartmouth Institute for Health Policy and Clinical Practice, Hanover NH.

Astrid Guttman, MDCM, MSc; Scientist, Institute for Clinical and Evaluative Sciences; Assistant Professor, Department of Pediatrics, University of Toronto; and Staff, Divisions of Pediatric Medicine and Emergency Medicine, Hospital for Sick Children, Toronto, ON.

Brian H. Rowe, MD, MSc; Research Director and Canada Research Chair, Department of Emergency Medicine, University of Alberta; Co-Director, Evidence-based Practice Centre, University of Alberta; Staff Physician, Emergency Medicine, Capital Health; Professor, University of Alberta, Edmonton, AB.

Brian Golden, PhD; Sandra Rotman Chair in Health Sector Strategy at The University of Toronto and The University Health Network Executive Director, Rotman Centre for Health Sector Strategy Professor of Strategic Management Rotman School of Management, University of Toronto, Toronto, ON.

Amit Nigam, PhD; post-doctoral researcher, the Rotman School of Management, University of Toronto, ON; and Associate Professor, New York University Wagner School of Public Service, New York City, NY.

The following individuals provided invaluable expertise, guidance and contribution to the selection of measures:

Howard Abrams; Dante Morra, MD; Matthew Cooke, MD, PhD; Christopher Baggogley; Ken Gardener, MD; Ken Deane; Bonnie Adamson; Debra Carew; Mark Afilalo, MD; Michael Carter, PhD; Anne Sales, BScN, PhD; Carolyn Baker; Bob Kocher,; Paul Mango; Heather Sharard.

Funding sources acknowledgements:

The Ontario Ministry of Health and Long-term Care (MOHLTC), Canadian Health Services Research Foundation (CHSRF); and The Canadian Institutes for Health Research (CIHR) provided support for this study and preparation of this manuscript. Partners at the MOHLTC collaborated with the research team on the study design, participated in the expert panel review process to select minimization factors and input on this manuscript. CHSRF and CIHR provided funding only.

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Table 1. Main themes of candidate minimization factors

- Leadership/staff concern/prioritization of patient flow issues
- Historical experience with change initiatives (such as: total number in the past year, intensity of previous initiatives upon staff, number of planned initiatives for the upcoming year);
- Organizational infrastructure (such as: # of General Internal Medicine beds, effectiveness of bed management, Information Technology and decision support etc.);
- Communication culture across professional groups;
- Capacities for participatory and collaborative engagement (such as: assessments of staff burn-out and staff capacity/resistance to lead, finance, or resource a change initiative);
- Importance of added values embedded in the intervention (such as: training opportunities, communication development strategies)

Table 2: Factors relating to achievement of a patient flow improvement – organizational change policy intervention				
Change Stage 1: Organizational Goals & Architecture	Assessment Domains			Mean
	Organizational Readiness	Predictive of successful implementation	Capacity to manage change	
Please tell us to what extent your organizational leadership and/or organizational staff are concerned about ED-GIM (Emergency Department - General Medicine) flow issues in your hospital:	7.7	6.7	5.4	<u>6.6</u> 7
ED-GIM flow issues in my hospital represent a critical challenge to our mission:	7.6	7.3	5.7	<u>6.6</u> 7
How high on your priority list would you place an initiative dealing with ED-GIM flow?	7.9	7.5	5.8	<u>7.1</u> 7
Is General Internal Medicine (GIM) / General Medicine a core clinical priority for your hospital?	6.7	6	5.2	<u>6.0</u> 6
Change Stage 2a: Organizational Readiness for Change				
Please tell us your previous experience with organizational change initiatives: How many MAJOR organizational change initiatives have taken place or have been planned in the past year (2008/2009).	6.1	5.8	5.2	<u>5.7</u> 6
Thinking about your hospital, what is the significance of: Staff burn-out from past change initiatives, as a potential barrier to improvements in ED flow and efficiency?	6.5	6.6	5.5	<u>6.2</u> 6
Thinking about your hospital, what is the significance of: Physician resistance to change, as a potential barrier to improvements in ED flow and efficiency?	7.3	7.7	6.6	<u>7.2</u> 7
Change Stage 2b: Situational analysis and redesign of organizational systems				
Thinking about your hospital, what is the significance of: Current communication practices between physician leadership and front-line nursing management, as a potential barrier to improvements in ED flow and efficiency?	6.4	6.8	5.4	<u>6.2</u> 6
Thinking about your hospital, what is the significance of: Current lack of coordination between ER and internal medicine on bed management issues, as a potential barrier to improvements in ED flow and efficiency?	6.9	7.2	5.7	<u>6.6</u>

Thinking about your hospital, what is the significance of: Current lack of physician coverage in the ED, as a potential barrier to improvements in ED flow and efficiency?	6.5	6.3	5.5	6.1
Change Stage 3: Capacity to build coalitions, broaden support and align systems				
Considering previous change initiatives your hospital has undertaken, were you able to develop effective communication methods, systems and strategies within and between medical/clinical services and sub-specialists within your hospital?	6.3	6.5	5.9	6.2
Thinking about your hospital, what is the significance of: Mis-alignment between physician incentives and goal of patient flow improvement, as a potential barrier to improvements in ED flow and efficiency?	6.8	7.4	6.5	6.9

Table 3. Minimization Variables

<p>Change Stage 1: Organizational Goals & Architecture To what extent would an initiative aimed to optimize in-patient flow and reduce Emergency Department length of stay be considered as the foremost priority for your hospital's leadership in 2009-2010?</p>
<p>Change Stage 2a: Organizational Readiness for Change How would you rate receptiveness to organizational change among physicians currently practicing at your hospital?</p>
<p>Change Stage 2b: Situational analysis and redesign of organizational systems How would you rate the efficiency of bed management / coordination currently in practice between the Emergency Department and in-patient medical care units at your hospital?</p>
<p>Change Stage 3: Capacity to build coalitions, broaden support and align systems State the degree to which physician incentives at your hospital are supportive of an organizational goal to optimize in-patient flow and reduce Emergency Department length of stay.</p>

Appendix 1: Candidate Factors by Change Stages

Change Stage 1 – Organizational Goals & Architecture

1. To what extent is your organizational leadership and/or organizational staff concerned about ED-GIM (Emergency Department - General Medicine) flow issues in your hospital
2. ED-GIM flow issues in my hospital represent a critical challenge to our mission.
3. How high on your organization’s priority list would you place an initiative dealing with ED-GIM flow?
4. Is General Internal Medicine (GIM) / General Medicine a core clinical priority for your hospital?
5. What proportion of beds in your hospital are dedicated General Internal Medicine (GIM) / General Medicine beds?

Change Stage 2A – Organizational Readiness for Change

6. How many change initiatives has your hospital completed in the past 4 years?
7. How many MAJOR organizational change initiatives have taken place or have been planned in the past year?
8. In general, how would you rate your hospital’s success with previous organizational change initiatives?
9. In general, how would you rate your staff’s capacity to lead and participate in policy and management change initiatives?
10. Are you aware of any major institutional change initiatives or challenges that your hospital will face in the next year?
11. In the last year has your hospital experienced any event that you would consider to be a crisis?
12. How long has your current CEO been in place?
13. How long has your hospital’s Physician in Chief (PIC) been in place?
14. How long has your hospital’s Nurse in Chief (NIC) or head of Nursing been in place?
15. Are the current lack financial resources for performance improvement initiatives a potential barrier to improvements in ED flow and efficiency?
16. Is the current lack of GIM beds in your organization/facility a potential barrier to improvements in ED flow and efficiency?

17. Is difficulty recruiting/retaining nursing staff a potential barrier to improvements in ED flow and efficiency?
18. Is a current state of staff burn-out from past change initiatives a potential barrier to improvements in ED flow and efficiency?
19. Is physician receptiveness/resistance to change a potential barrier to improvements in ED flow and efficiency?
20. Does your hospital currently have a staff position or positions dedicated to leading and managing change initiatives?

Change Stage 2B – Situational analysis and redesign of organizational systems

21. Is a current lack of IT/decision support infrastructure at your hospital a potential barrier to improvements in ED flow and efficiency?
22. Are current communication practices between physician leadership and front-line nursing management a potential barrier to achieving improvements in ED flow and efficiency?
23. Is there a current lack of coordination between ER and internal medicine on bed management issues at your organization?
24. Is there a current lack of physician coverage in the ED at your organization?

Change Stage 3 – Capacity to build coalitions, broaden support and align systems

25. In general, how would you rate your staff's receptiveness to support change initiatives?
26. Considering previous change initiatives your hospital has undertaken, how important do you think it is to include: Training opportunities?
27. Considering previous change initiatives your hospital has undertaken, how important do you think it is to include: Facilitating local ownership through consultation?
28. Considering previous change initiatives your hospital has undertaken, how important do you think it is to include: C) Development of effective communication methods, systems and strategies within and between medical/clinical services and sub-specialists within your hospital?
29. Is mis-alignment between physician incentives and goal of patient flow improvement a potential barrier to improvements in ED flow and efficiency?
30. Are existing communication practices between different professional groups in the organization/facility on the whole a potential barrier to improvements in ED flow and efficiency?

31. Is timely review of the Emergency Department consults to clinical services (diagnostic imaging and sub-specialist consultation) a potential barrier to improvements in ED flow and efficiency?
32. Does your hospital require the involvement of sub specialists prior to providing access to certain diagnostic imaging tests or reading/interpretation of tests for the Emergency Department?
33. Does access to clinical and/or medical services in your hospital have priority over the Emergency Department?