INTRODUCTION

A major change in peripheral intravenous catheter (PIVC) policy in the past decade has been in criteria for PIVC removal - from a time-based policy to a policy based on clinical criteria.[1, 2] After an outbreak of bloodstream infections in the early 1970s, the Centers for Disease Control and Prevention (CDC) recommended 24 hourly PIVC removal and replacement, instead of previous clinically determined removal.[3] Although the outbreak was ultimately traced to manufacturer contaminated fluid, routine removal remained common policy, extended gradually by the CDC to 48 hourly, 72 hourly, and then 72-96 hourly removal.[4] Such policies required patients to undergo repeated PIVC insertion procedures to replace even functional, comfortable catheters, in order to complete infusion therapy. Contemporary evidence supports PIVC replacement by “clinical indication” which relies on patient-centered, clinical decision making to appropriately remove PIVCs.[5] Clinicians must continue to regularly examine PIVC insertion sites, ask patients about symptoms, and consider planned treatment, but it is also now imperative that they act on these findings to remove catheters that are no longer needed, not-functioning, uncomfortable, suspected of infection, or were inserted without appropriate infection prevention standards (e.g. in an emergency situation).[5]

Evidence to support the policy change is substantial including a Cochrane systematic review released in 2011 and updated in 2019 that includes 9 RCTs, concluding “no evidence to support routine catheter change every 72-96 hours”. [6] The largest RCT (3283 patients) found almost identical complication rates of 68 vs 66 per 1000 PIVC days for clinically indicated and routine removal respectively, with significantly reduced costs, staff time, and patient discomfort with clinically indicated removal.[7] Similarly, there was no difference in phlebitis or catheter-related bloodstream infection between the 2 removal approaches.[6] Additional
large RCTs from China and Brazil had consistent findings\textsuperscript{[8, 9]} and a global observational study of over 40,000 PIVCs found PIVC dwell was not associated with phlebitis.\textsuperscript{[10]}

**Implementation into policy**

Government and professional bodies have progressively incorporated clinically indicated removal recommendations. In 2011, the CDC advised “there is no need to replace PIVCs more frequently than every 72-96 hours” (p.16), but also “no recommendation is made regarding replacement of peripheral catheters in adults only when clinically indicated: (p.16).\textsuperscript{[4]} In the same year, the *Infusion Therapy Standards of Practice* recommended PIVC clinically indicated removal now \textsuperscript{[2]} defined as: “1) any level of pain/tenderness with/without palpitation; 2) changes in colour, 3) changes in skin temperature; 4) oedema; 5) induration; 6) purulent discharge or leakage of fluid from the site; and/or 7) other types of dysfunction (flushing and aspiration difficulties)” (Pg. s91).\textsuperscript{[11]} In 2011, the Swedish Nursing Association advocated clinically indicated removal with an individualized approach considering catheter material and insertion site, composition of infusion/medicine, fixation method, patient difficulty and insertion by an IV Team.\textsuperscript{[12]} Implementation in the UK followed the 2014 *Epic 3: National Evidence-Based Guidelines for Preventing Healthcare-associated Infections in NHS Hospitals in England* recommendation that PIVCs “should be re-sited when clinically indicated and not routinely, unless device-specific recommendations from the manufacturer indicate otherwise” (pg10).\textsuperscript{[1]} More recently, all major medical specialties in Spain released a consensus recommending clinically indicated PIVC removal.\textsuperscript{[13]}

**Implementation into practice**

While the past decade has seen many major international guidelines adopt clinically indicated removal, anecdotally, there has been slow uptake into clinical policy and practice at the local hospital level. In a recent worldwide survey,\textsuperscript{[10]} only one-third of hospitals had taken up the policy (data on file). The transition from any new innovation to routine clinical practice is
challenging and typically has a 17 year time lag\textsuperscript{[14]} even after major guidelines recommend implementation. In the case of clinically indicated removal, it is likely that the absence of a strong recommendation endorsing clinically indicated removal from the CDC was one delaying factor. Another may have been reluctance to generalize results of Australian trials to other health systems, although recent confirmatory trials have been undertaken elsewhere.\textsuperscript{[8, 9]} Finally, no published framework exists to guide implementation of clinically indicated removal policy, suggesting hospitals need guidance to overcome the barriers to change that exist at the patient, clinician, organizational, and outer regulatory body level.\textsuperscript{[15]}

**Implementation using the CFIR framework**

The Consolidated Framework for Implementation Research (CFIR) combines constructs from numerous published implementation theories.\textsuperscript{[15]} CFIR has 5 major domains: intervention characteristics, outer setting, inner setting, characteristics of the individuals involved, and the process of implementation (Supplemental Digital Content).\textsuperscript{[15]} Each domain reflects an important component in the process that leads to implementation and service outcomes. We evaluated the adoption of clinically indicated PIVC removal policy, against CFIR’s 5 domains and provide a discussion and critique of salient strategies for successful implementation of this change into practice and policy in health care settings. Standards for Quality Improvement Reporting Excellence (SQUIRE) 2.0 were used to prepare this manuscript.

**APPROACH**

CFIR domains offer salient implementation strategies for successfully transforming practice and policy towards clinically indicated PIVC removal (figure 1):

**CFIR 1: Intervention Characteristics**
The components of CFIR indicate that implementation of clinically indicated PIVC removal should be perceived as attractive since it has high quality supporting evidence, is patient-centered, and will likely succeed in meeting local patient and health service needs if education and feedback support are provided.

**Patient Centered Evidence Based Practice**

The evidence supporting clinically indicated PIVC removal is compelling, and therefore can disrupt routine replacement practice, and trigger policy change. Evidence includes several RCTs,[7] and a Cochrane Systematic Review.[6] Other evidence types can also be influential, for example the Infusion Therapy Standards of Practice[11] and national guidelines from UK, Spain and other countries.[1, 13] Such evidence is likely to gain support from bedside clinicians for whom it is clinically meaningful to leave PIVCs in place where still needed, complication-free and functional, rather than removing catheters which triggers additional insertion procedures. PIVC inspections each shift are already standard practice and thus involve no extra work for nurses. However, while existing assessments are embedded practice, clinically indicated removal requires additional decision-making based on these assessments that may have been neglected under a more simplistic time-based policy. Patients’ needs to reduce pain and vessel damage from multiple PIVC insertions are well known by clinical staff and the current emphasis on patient-centered care can be a further motivator and catalyst for implementation.[16]

Clinical leaders are likely to perceive implementation as advantageous when presented with the evidence about advantages in staff workloads and costs, without increased adverse events.[6] In addition, local experiential knowledge about the concept of clinically indicated removal already exists, since 96 hourly removal is not always possible or is deliberately extended in patients with difficult access or other supporting circumstances, and has always
been the policy in pediatrics.\textsuperscript{[4, 17]} All clinicians are familiar with PIVCs, so motivating the multi-disciplinary team (including infection control, infectious disease, nursing, safety and quality, vascular access, and resource management) to focus on benefits of fewer, painful, unnecessary procedures, preserving blood vessels, and improved patient satisfaction, is key. A particularly important point is that the costs of implementation must be considered and agreed to before the project onset to engender a shared culture of understanding regarding the end benefit of undergoing change.

\textit{Local Needs}

Implementation can be promoted as an opportunity to develop a local ‘bundle’ of interventions that improve all aspects of PIVC use, to target local problems of PIVC bloodstream infections, Staphylococcus aureus bacteremia (SAB), and other complications such as phlebitis and occlusion that concern policy makers and clinicians. Clinically indicated implementation in the USA\textsuperscript{[18]} comprised a bundle of improved PIVC insertion and maintenance interventions, terming this “protected clinical indication” and addressed a local problem of primary bacteremia. The bundle included a focus on better insertion, antimicrobial dressings, improved securement, and continued to evolve after initial implementation with additional product changes as needed in response to local needs.\textsuperscript{[19]}

The perceived local needs of health care facilities to prevent infection but also avoid failed insertion procedures provides a basis for clinically indicated removal as logical and intuitive. Routine replacement can trigger delayed or failed PIVC replacement insertions which delays treatment and potentially discharge.\textsuperscript{[20, 21]} If there is local history of patients with poor peripheral veins having complication-free PIVCs allowed to dwell for longer periods then formal adoption of clinically indicated removal merely formalizes existing passive implementation. Or, a ‘stepped’ implementation process where policy is first formally
changed only for difficult access patients may generate clinician confidence through experience and local data to build a supportive culture to expand the policy to all patients.[22]

**Education and feedback**

Successful implementation requires education and feedback for frontline staff to make appropriate decisions which require confidence and competence with PIVC site assessment, indicators for removal, and negotiating decisions amongst the care team.[23] To successfully support staff in this change, workflows need to be reconfigured so as to hardwire education and feedback into daily practice, making the “right decision” the “easy decision” every time. Point-of-care comprehensive, frequent, PIVC assessment should be inbuilt into the medical record, with prompts for appropriate action based on negative findings (e.g. if no intravenous therapy is prescribed, prompts to justify non-removal should occur).

Initial and ongoing educational support incurs costs including educator time, time for staff to attend sessions, tailoring and reprogramming of health records. In addition are costs for modifying e-learning webpages, policy manuals and audits to embed the new protocol. These need to be considered in a business case for implementation, with cost-benefits also articulated. This includes reduced staff time and equipment costs for PIVC replacements and costs associated with treatment interruptions from delayed/failed insertions. New mechanisms for regular audit and feedback to bedside staff about their achievements in appropriate removals and improved patient outcomes are crucial to embed as part of the implementation.

**CFIR II. Outer setting**

The outer setting includes the economic, political, and social context within which organizations reside.[15] External driving forces strongly influence successful implementation.

**External driving forces**
The external driving forces of PIVC removal policies include organizational bodies such as regional or national health boards/departments and national professional organizations such as nursing, infection control and vascular access societies. Higher hierarchial bodies such as national health departments and societies who recommended clinically indicated removal[1, 12, 13] can facilitate local approval from nursing and medical leaders and local health boards. Such bodies often promote guidelines via websites, email distribution lists, social media and promotional materials, hence influencing bedside clinicians. Mass adoption on a broader scale tends to be created through peer pressure. Financial incentives or disincentives can also be powerful, particularly where payors require certain quality targets to be met. National clinical care standard for PIVCs can ultimately be linked to accreditation, facilitating institutions to develop documentation and processes to ensure safe removal as part of the broader safe use of these devices.[24]

**CFIR III. Inner setting**

The inner setting features structural, political, and cultural contexts through which implementation processes proceed.[15] Three important inner setting areas are: PIVC inserter as stakeholders, strong leadership, and easily accessible resources.

**PIVC inserter as stakeholders**

Garnering support from clinical staff directly responsible for insertions is vital for appropriate removal decision-making and successful implementation. Hospitals have myriad medical and nursing staff undertaking PIVC insertions and therefore multi-professional involvement in implementation is necessary at multiple levels of the organization (e.g. junior clinicians to nursing/medical educators and departmental directors).[25] Unfortunately, multiple care providers can lead to reluctance to address problems given social and behavioral tendencies e.g. ‘bystander effect.’[26] Champions need to be prepared to work outside their specialty since
implementation requires inter-professional solutions (i.e. nursing, infection prevention/infectious diseases, safety and quality, clinical management and education, anesthetics, radiology, and vascular access). Where whole facility implementation cannot be achieved due to inadequate stakeholder support, stepped implementation (e.g. in the medical division alone) may be achievable with potential to later extend facility-wide.

**Strong leadership**

Successful implementation requires strong leadership.\cite{15} De Vries et al.\cite{18} demonstrated the value of a leadership team with explicit desire to improve patient experiences when tasked with implementing clinically indicated PIVC removal and evaluating its impact. They reviewed standards, and presented practice change elements and projected benefits to managers.\cite{18} The team included an internationally-respected infection preventionist who could articulate local PIVC related risk issues that supported investment in prevention.\cite{18} An organizational history of evidence-based recommendations to benefit patients, a culture of measuring impact and strong inter-professional collaboration were noted as drivers of success. In other organizations, the individual spearheading implementation could be a vascular access, physician or a nursing leader with support from an executive sponsor (e.g. director of nursing or infectious diseases). The sponsor must be briefed, then along with the project initiator establish a working group to drive change, engage stakeholders, identify and overcome barriers.\cite{18} High-level support is vital to ensure implementation resources (e.g. a project manager, and resources to collect and review audit data) that sustain motivation and behavior change.\cite{27, 28}

**Easily accessible resources**

Clinical change requires multiple strategies for different stakeholders, but ‘point of care’ support for PIVC removal decision making is vital.\cite{29} This must include good quality, easily
accessible education resources combined with feedback for frontline staff to engender confidence and autonomy in clinical decision making on appropriate PIVC removal. Dr. Mermel author of the Infectious Diseases Society of America infection prevention guidelines, commented on PIVC removal that “it’s best to make things simple and easy to follow and have black-and-white rules of what to do”.[30] Adoption of clinically indicated removal therefore needs new, simple algorithms such as the I-DECIDED tool which prompts care and removal decisions by aggregating clinical guidelines into a simple mnemonic.[31] Nursing commentary has recommended education of patients, family members, and clinicians on how to assess for complications and decide on PIVC removal, plus the need to regularly audit local outcomes.[32] Accessible material for busy clinicians might include electronic or paper-based support tools at the bedside and as e-learning packages that allow flexible delivery. Initial education sessions, and after-hours bedside teaching must be followed by visual materials that reinforce regular PIVC assessments and appropriate removal criteria. Consistency of education materials between medicine, nursing and departments is crucial. Furthermore, annual mandatory competency assessment for PIVC maintenance and removal could be added to the existing insertion-only competencies, in order to address regular staff turnover and to sustain change.

**CFIR IV. Characteristics of individuals**

Individuals within an organization heavily influence implementation.[15] This is particularly true for changing to a patient-centered decision, whereby clinicians, generally nurses, must enact more autonomy in decision making than under the previous time-driven criteria.[21, 31] Heightened autonomy requires individuals to cognitively understand the new policy and their role in it. This requires knowledge of how to decide which PIVCs to remove, and the confidence to make this decision and communicate it with the care team. Positive or negative
affective feedback (e.g. medical staff support or criticism regarding nurses’ PIVC removal decisions) will influence individuals’ future behavior. Additionally important is belief in the ability to provide replacement insertions for those patients needing ongoing therapy after a PIVC is removed. Under the new policy, PIVC removal occur at any time of day, but advanced inserters (who may once have undertaken routine replacements) may only work business hours. Experiencing ‘success’ personally and in the organizational workflow with the new policy will build confidence that reinforces individuals’ self-efficacy and behavior. Scope of practice, and escalation pathways may need clarification, as there is variation internationally in nurses’ role in PIVC insertion and the availability of advanced inserters.[10]

Implementation can benefit clinicians at the individual level by enhanced professional competence via active learning and ability to precisely assess, act on their assessment, and document the PIVC every shift. This is as an opportunity for upgrading clinical skills and knowledge to enjoy the full scope of practice and professional decision making at the point of care.

**CFIR V. Process**

Successful implementation requires active change involving interrelated sub-processes that can be formally planned, or spontaneous.[15]

**Planning**

De Vries et al.[18] report preparations to initiate clinically indicated PIVC removal require approximately 6 months, during which time existing professional standards and literature, internal policies and practice audits must be reviewed to refine implementation strategies. This important period prepares the education and feedback systems that will motivate the inner setting and engage strong, influential local leaders. During this time, it is crucial that the correct stakeholders are involved who have the willingness and aptitude to spend hours on
social interventions (which require humility, patience and inter-professional approaches), and that indicators for success are clearly defined by the team.\textsuperscript{[26, 29]}

**Engaging and Executing**

Within this dimension, strong leadership and connecting and interacting with stakeholders remains key to execute the policy and practice change. Practice changes will be facilitated by by attracting and involving others through education using posters and training with audit and feedback systems.\textsuperscript{[15]} Engagement with the outer setting should continue to enhance organizational capacity, credibility and enthusiasm for change through social marketing and role modelling.\textsuperscript{[15]} While strong supportive leadership is key, even unsupportive organizational stakeholders must be engaged, with feedback systems that can allay concerns and value the effort of change.\textsuperscript{[33]} Execution can be carried by dry runs (simulations or practice sessions before going live), pilot trials, or incremental interventions depending on what is suitable for the organization.\textsuperscript{[15]}

**Reflecting and Evaluating**

Dr O’Grady, lead author of the CDC Guidelines, cautions \textit{“if you go to an as-needed (PIVC removal) policy, one could become less rigorous about changing it. You have to pay close attention to the catheter daily for signs of phlebitis.”}\textsuperscript{[30]} Thus, surveillance is needed to monitor the safety and effectiveness of the new policy, with feedback to front line staff including celebrations of success for staff engagement. Audit data on reasons for PIVC removal reveal device failure trends, which can inform future quality improvement projects.

One hospital reported a 19\% reduction in PIVC bloodstream infections\textsuperscript{[18]} following implementation – such data provided positive reinforcement for frontline clinical staff. Consequently, their infection prevention staff undertake weekly audits of every catheter including dwell time, reason for removal, insertions in the ER/inpatient units, gauge, and
anatomical site to identify “real time” trends (rather than the previous annual audit). In addition, monthly bedside audits of >1000 PIVCs focus on process measures to document site assessment, administration set date compliance, presence of chlorhexidine gluconate sponge and alcohol caps, and dressing integrity. Audit results are provided regularly to staff to reinforce consistent understanding about appropriate criteria for PIVC removal. At 2 years post-implementation, the hospital reported 20% of PIVCs remained functional at 7 days and 35% after 5 days[19]. Such data remind stakeholders of benefits and sustain the policy.

Ongoing internal feedback was an overlapping theme for the Intervention characteristics, and Process constructs of CFIR. Access to, and review of PIVC surveillance data and documentation reassure stakeholders that there is no harm from the new policy. For example, implementation of clinically indicated removal in one NHS Trust in the UK incurred unease from the Infection Prevention Action Group due to fear of impacting local health care associated infections.[34] Six months after implementation PIVC-associated outcomes were not adversely affected, costs were significantly reduced, and 11,750 clinical hours were saved from unnecessary PIVC insertions, which convinced the Trust to fully implement the new policy.[34] Therefore, regular auditing and reporting can allay real or perceived concerns.

**CONCLUSION**

Clinically indicated removal has long been the norm in pediatrics and an unofficial policy in difficult to cannulate adults to avoid multiple, painful insertion attempts. Now that evidence strongly supports clinically indicated PIVC removal for all patients, implementation requires a focused effort which can be achieved through planned processes using the CFIR framework. Specific considerations include emphasis of the patient-centered, evidence-based nature of the intervention, policy change to meet existing local needs, provision of quality, accessible education and resources, and regular audit and feedback to clinical staff.
References:


