Journal Pre-proof

National implementation of a pragmatic quality improvement skills curriculum for urology residents in the UK: Application and results of 'theory-of-change' methodology

Ms Zuhur Balayah, Dr Zarnie Khadjesari, Dr Aoife Keohane, Dr Wilson To, James SA. Green, Nick Sevdalis

PII: \$0002-9610(20)30785-6

DOI: https://doi.org/10.1016/j.amjsurg.2020.12.007

Reference: AJS 14170

To appear in: The American Journal of Surgery

Received Date: 13 June 2020

Revised Date: 30 November 2020 Accepted Date: 2 December 2020

Please cite this article as: Balayah MZ, Khadjesari DZ, Keohane DA, To DW, Green JS, Sevdalis N, National implementation of a pragmatic quality improvement skills curriculum for urology residents in the UK: Application and results of 'theory-of-change' methodology, *The American Journal of Surgery* (2021), doi: https://doi.org/10.1016/j.amjsurg.2020.12.007.

This is a PDF file of an article that has undergone enhancements after acceptance, such as the addition of a cover page and metadata, and formatting for readability, but it is not yet the definitive version of record. This version will undergo additional copyediting, typesetting and review before it is published in its final form, but we are providing this version to give early visibility of the article. Please note that, during the production process, errors may be discovered which could affect the content, and all legal disclaimers that apply to the journal pertain.

© 2020 Published by Elsevier Inc.



Journal Pre-proof

National implementation of a pragmatic quality improvement skills curriculum for urology residents in the UK: Application and results of 'Theory-of-Change' methodology

Ms Zuhur Balayah¹, Dr Zarnie Khadjesari², Dr Aoife Keohane¹, Dr Wilson To³, Professor James SA Green^{1,3*}, Professor Nick Sevdalis^{1*}

¹Center for Implementation Science, Health Service and Population Research Department, King's College London, UK

Correspondence: Ms Zuhur Balayah, Center for Implementation Science, Health Service and Population Research Department, Institute of Psychiatry, Psychology and Neuroscience, King's College London, De Crespigny Park SE5 8AF, UK; email: zuhur.balayah@cass.city.ac.uk

Funding: The research was funded by the Urology Foundation. The Urology Foundation is grateful for the support of the Schroder Foundation on this project. NS and AK's research is supported by the NIHR Applied Research Collaboration South London at King's College Hospital NHS Foundation Trust. NS is also member of King's Improvement Science, which is part of the NIHR CLAHRC South London and comprises a specialist team of improvement scientists and senior researchers based at King's College London. Its work is funded by King's Health Partners (Guy's and St Thomas' NHS Foundation Trust, King's College Hospital NHS Foundation Trust, King's College London and South London and Maudsley NHS Foundation Trust), Guy's and St Thomas' Charity, and the Maudsley Charity. No funding source had any role in the design and conduct of the study; collection, management, analysis or interpretation of the data; or preparation, review or approval of the manuscript. The views expressed are those of the authors and not necessarily those of the Urology Foundation, NHS, the NIHR or the Department of Health and Social Care.

Page count (main manuscript text): 17 pages

²School of Health Sciences, University of East Anglia, Norwich, UK

³Bart's Health, Whipps Cross Hospital, Urological Department, London, UK

^{*}These two authors (JSAG and NS) have contributed equally to the research and to the manuscript and are joint senior authors

ABSTRACT

Background: There is global momentum to establish scalable Quality Improvement (QI) skills training curricula. We report development of an implementation plan for national scale-up of the 'Education in Quality Improvement' program (EQUIP) in UK urology residencies. **Materials & Methods:** Theory-of-Change (ToC) methodology was used, which engaged EQUIP stakeholders in developing a single-page implementation 'Logic Model' in 4 study phases (2 stakeholder workshops (N=20); 10 stakeholder interviews). The framework method was used for analysis.

Results: Core elements of the EQUIP Logic Model include: (i) QI curriculum integration into national surgical curricula; (ii) resident-led, modular, team-based QI projects; (iii) development of a national web-platform as QI projects library; (iv) a train-the-trainers module to develop attendings as QI mentors; and (v) knowledge transfer activities (e.g., peer-reviewed publications of residents' QI projects).

Conclusions: ToC methodology was useful in developing a stakeholder-driven, actionable implementation plan for the national scale-up of EQUIP in the UK.

KEYWORDS: urology; quality improvement; education; Logic Model; Theory of Change; implementation science

INTRODUCTION

For the past two decades, surgery as a specialty has been at the forefront of patient safety and quality improvement (QI). The complex and invasive nature of surgical care, which typically requires successful interactions between complex healthcare systems, new technologies and reliable delivery of evidenced, standardized care pathways (e.g., enhanced recovery programs) calls for focused attention on the need to identify gaps and lapses in surgical skills and care delivery and to address them. Numerous interventions have been pioneered within surgery with a view to improve quality and safety— e.g., simulation technologies, focus on non-technical skills and human factors, and introduction of checklists, to name a few.

Surgical education has evolved to support these developments. With the support of simulation centers and newly developed surgical technical, ^{7.8} non-technical, ^{9,10} and surgical leadership skills frameworks, ¹¹ surgical curricula have increasingly integrated patient safety and the skills required to assess and enhance it within a surgical service.

The same level of maturity, however, is yet to be reached within surgical education in relation to imparting skills to residents in improving quality of surgical services.

Improvement Science, defined as the systematic application of scientific methods aimed at improving the outcome and experience of care for patients, ¹² has advanced significantly in the past 20 years. A number of tools and techniques developed in other industries (e.g., manufacturing) have been trialled and adapted for use within healthcare – e.g., the Model for Improvement, or 'lean' approaches. ¹³ Numerous examples of successful applications that improved efficiency and outcomes in care delivery have been published and reviewed. ¹⁴ Todate, however, surgical curricula have not achieved a systematic integration of such techniques: Residents are only patchily exposed to QI techniques as part of their training. This creates a capacity gap for QI within surgery.

The EQUIP research program

The 'Education in Quality Improvement Program' (EQUIP) was launched in 2017 to address this gap within surgical training. The program aims to develop an evidence-based, user-informed, practical and scalable QI skills training curriculum for surgical residents. To ensure feasibility, the program has initially focused on urology training in the UK, with the vision that once the evidence-base that supports it is established EQUIP could be applied to other surgical specialties. Key findings of the EQUIP to-date include:

- A national training needs assessment of urology residents found significant variations in exposure to QI skills training and engagement with the design and delivery of clinical improvement programs in the residents' departments. 15
- Evidence reviews on how QI skills are best taught within healthcare and surgery have revealed consistently that delivery should include a dual focus on theory and practical application. This includes workshop-based, interactive sessions with residents, so that residents can absorb the QI techniques through direct application to specific clinical issues. ^{16,17} No single best QI technique exists, but knowledgeable application of the selected QI technique to the clinical problem at hand is necessary.
- Based on the above, a pragmatic half-day training module has been developed, with inputs from residents, attendings, nurses, managers, patients, and education and improvement science experts. The module has shown educational efficacy and feasibility. Since 2018, the QI module has become part of the UK's Annual Urology Bootcamp (1-week long intensive simulation-based residential training; www.surgicaltrainingnetwork.org/urologybootcamp), which is mandatory for residents going into the specialty and reaching approximately 50 residents annually.

The evidence above suggests that EQUIP offers a viable QI training approach for surgical residents. What remains unclear, however, is how precisely EQUIP could move from a research program to a nationally deliverable and sustainable educational program within UK urology. This is a major transition for educational and clinical research alike; some evidence suggests that it takes an average of 17 years for scientifically proven interventions to become routinely applied within healthcare organizations. ¹⁹ The gap between scientific evaluation and clinical application is commonly described in the literature as an 'implementation gap'. ²⁰ The study we report here aims to address this gap, through addressing two aims, both of them of qualitative nature. The primary aim of the study was to apply 'Theory-of-Change' (ToC) methodology to produce a stakeholder-driven national implementation plan for EQUIP to be routinely scaled across UK urology departments and training programs. The secondary aim of the study was to appraise the feasibility and utility of using ToC methodology in the context of surgical education, where it is currently not commonly reported.

MATERIAL AND METHODS

Study design

This was a prospective study using ToC methodology, which is qualitative. Ethics approval for this study was issued by King's College Research Ethics Committee (MRA-18/19-12641). Informed consent was obtained from all participants before participation.

Theory-of-Change methodology

ToC is a well-established methodology, originally developed to evaluate complex health (and other, e.g., international development) program implementation and effectiveness.^{21,22}

Programs, as opposed to single interventions, often consist of multiple interventions or

components, delivered to multiple stakeholders at different times; they tend to be large (e.g., regional or national) and their implementation and ultimate effectiveness can be to a large extent affected by the quality of delivery. ToC methodology was developed to articulate the underlying assumptions about precisely how the anticipated effect will materialize when a program is delivered, what will impact on it and what may drive or impede it – including identification of stakeholders (individuals and organizations with an interest in and ability to impact on the program). Development of a ToC is recommended before large-scale program implementation. ^{23,24} A ToC can be used to plan and develop the program appropriately and identify implementation barriers and 'bottlenecks' ahead of the implementation phase, so that they can be addressed pre-emptively. Best practice in ToC application requires involvement of a wide range of stakeholders in the development of the ToC and establishing consensus amongst them on the ToC elements; consensus is established qualitatively, through successive iterations of the ToC until stakeholders view it as accurate and comprehensive. In addition to the technical objective of specifying how a program may reach its intended objectives, a well-developed ToC also serves the objective of engaging the program stakeholders and communicating with them: because ToCs are developed with stakeholders, this direct involvement allows them to better understand program components and develop a sense of program 'co-ownership'. This means that the research process itself (i.e., doing the study) becomes a mechanism that support future implementation. Being a qualitative technique, ToC development is typically achieved through interactive workshops. A finalized ToC tends to take the visual form of a 'Logic Model', ²⁵ which is a single-page visual representation of a program that links all the ToC elements into a logical 'Program inputs \rightarrow Program activities \rightarrow Program outcomes \rightarrow Final program impacts' sequence. The final Logic Model representation of the ToC is used to guide program implementation.

ToC methodology is not commonly used in surgical education – however it was considered directly applicable to the development of an implementation plan for EQUIP. EQUIP is a programmatic educational intervention, envisaged to be implementable across UK urology residencies and departments. It therefore requires identification of and engagement with stakeholders at national level for sustainable implementation across the UK, within the existing national educational governance framework (i.e., the General Medical Council, surgical Royal Colleges and the British Association of Urological Surgeons (BAUS)). More precisely, we set-out to identify implementation strategies/questions concerning the following components of an implementation plan: how to embed QI curriculum into surgical curricula; defining scope and scale of residents' QI projects; specification and potential host for a QI web-platform; how to apply QI teaching at national scale; and identification of QI knowledge transfer strategies (to ensure residents and departments learn from each other's projects).

Participants and setting

Best practice requires ToC participants to be identified through stakeholder mapping – i.e., identification of individuals and organizations with interest and ability to influence EQUIP implementation. We used a 'snowball' approach to identify stakeholders. Firstly, the EQUIP Steering Group members were included as stakeholders – as they include urologist attendings, residents, specialist urology nurses, patients, healthcare managers, program funders and education and improvement science experts and have been engaged with EQUIP since inception in 2017. Steering Group members were subsequently asked to identify further stakeholders. The final sample for the study was determined through the saturation criterion: stakeholder recruitment ceased at the point when no further new themes were added to the ToC, i.e., when a consensus was reached regarding the ToC shape and content. Current recommendations for qualitative research suggest that saturation should start to

appear within 6-12 interviews.²⁷ We applied this principle in conjunction with best practice in workshop facilitation,²⁸ and planned workshops of up to 10 participants and 6-10 supplemental interviews.

Data collection

We followed established guidelines in applying the ToC method – as follows:

Phase 1: initial Logic Model development (Apr-May 2019)

An initial draft Logic Model was developed by the research team and was used as the basis for the 1st ToC workshop (see Phase 2), based on the EQUIP evidence base. ¹⁵⁻¹⁸

Phase 2: 1st ToC workshop (Jun 2019) & 1st set of stakeholder interviews (Jun-Sep 2019)

The workshop, attended by 10 participants, was structured as follows: (i) initial introduction to ToC methodology to orientate participants (10 mins), (ii) brief summary of EQUIP to-date (5 mins), (iii) statement of study aims and presentation of the Logic Model (draft 1, 5mins), (iv) small group discussions and editing of the draft Logic Model (60mins), and (v) summary and conclusion session (30mins). We used the last 30 mins of each of the workshop sessions - (i.e., the summary and conclusion session) to establish consensus. This was done by giving each group an opportunity to present their main discussion points to the whole group. Then any areas where there was disagreement were discussed further as a whole group.

Additionally, during the analysis of the workshop transcripts the lead coder (ZB) checked whether themes that emerged with strong support within workshop subgroups were also present in some form in other workshop groups (if they were, then the theme was retained as part of the thematic analysis and fed into subsequent workshop/interviews). Participants were asked to consider key questions, such as what activities should be undertaken to allow

national implementation and to articulate assumptions and enablers to achieve the objectives of EQUIP. The workshop was facilitated by ZB and ZK. The EQUIP clinical (JSAG) and academic (NS) leads left the room while participants undertook the editing of the Logic Model – to avoid biasing the participants in a specific direction.

The Logic Model resulting from the 1st workshop (draft 2) was presented to a group of new participants (N=6) in the context of semi-structured interviews, conducted by ZB. Participants were presented with the visual one-page Logic Model and were asked to review how acceptable and feasible they found it as an implementation plan for EQUIP; and to critique the proposed implementation strategies. Input from these interviews were used to edit the Logic Model prior to submitting it to the 2nd ToC workshop, for further development.

Phase 3: 2nd ToC workshop (Sep 2019)

The 2nd ToC workshop was attended by 10 participants (including some who had also attended the 1st ToC workshop (N=5) to ensure coherence of the Logic Model development process, but also some new participants (N=5) to ensure coverage of different perspectives). The workshop structure included: (i) reminder of the ToC process to-date (10mins), (ii) brief presentation of the revised Logic Model (draft 3, 20mins), (iii) small group discussions and editing of the Logic Model (60mins), and (iv) summary and conclusion session (30mins). Participants were instructed to focus on specific elements of the Logic Model, including: national delivery mechanisms for the QI curriculum; resident-led QI projects scope and scale; development of a QI national web-platform; and capacity building approaches. The workshop was facilitated by ZB and AK; as in the 1st workshop, JSAG and NS left the room while the Logic Model editing was carried out.

Phase 4: 2nd set of stakeholder interviews & Logic Model finalization (Sep-Oct 2019)

A final set of interviews with a new set of participants were conducted by ZB in autumn 2019 (N=4), in which the Logic Model (draft 4) as revised after the 2nd ToC workshop was presented for critique. The recruitment focus was on participants representing national UK organizations involved in regulating urologic services and education. Upon completion of these interviews, the Logic Model for EQUIP was finalized at the 5th iteration.

Workshops took place face-to-face and lasted 2hrs each. Interviews were conducted telephonically or face-to-face and lasted 30-60mins each. Workshops and interviews were audio-recorded and professionally transcribed for analysis.

Data analysis and Logic Model derivation

The Framework Method was used to analyse the data. ^{29,30} This approach was selected as it was appropriate for the study dataset (workshops and interviews); it provides a systematic model for mapping data in a thematic matrix form; and it allows large amount of transcript data to be summarized efficiently through charted thematic summaries. We applied all stages of the method – namely, familiarization with the dataset, identification of an overall thematic framework, indexing, charting, and finally mapping and interpreting the themes that emerge. The analysis was led by ZB, and subsequently reviewed by ZK (improvement/implementation scientists), AK (education program manager) and WT (urologist). We reviewed emerging codes during project research meetings, where input from the senior leads of the program (NS and JSAG and NS) was also sought to establish consensus-driven coding. This stepped approach to thematic coding was useful in bringing together clinical and scientific perspectives on the themes. Data from transcripts were

Journal Pre-proof

supplemented by the Logic Models as drafted in the ToC workshops, and the participants'

notes on them.

The analysis yielded 6 main themes (and 26 subthemes): QI curriculum; residents' QI

projects; national QI web-platform; national QI capacity building; QI knowledge transfer;

and enablers/barriers to EQUIP implementation. These were subsequently mapped onto the

Logic Model sections; reviewed by NS (senior improvement/implementation scientist) and

JSAG (senior attending urologist); and the final Logic Model was produced.

RESULTS

Individual and organizational stakeholders

The professional roles and bodies that were represented through the stakeholders included in

the study is summarized in Table 1. These cover the senior policy-makers and leaders of

urologic surgery, education and nursing in the UK and partly of Europe; national QI and

resident organizations; peer-reviewed journals with a UK focus; and a number of practising

clinicians, managers, academic scientists and patients.

Table 1

EQUIP Logic Model

Phase 1 (Figure 1)

Informed by prior EQUIP research, the initial Logic Model included the following activities

to be undertaken to support the national scale-up: embedding nationally the QI residents'

curriculum; engaging residents in undertaking QI projects; developing a web-platform to host

QI projects; developing capacity to teach QI skills; and scientific knowledge transfer, in the

11

form of establishing avenues to publish QI studies in urology. Unspecified elements of the model included how to deliver nationally QI training, what the scope and scale of residents' QI projects should be and how best to appraise them for quality, specification and host for the online QI platform and what the approach might be for the development of QI faculty to support the residents. The model further lacked specificity in the assumptions and enablers/barriers to successful implementation; and in assessing the final intended impact.

Figures 1 & 2

Phase 2 (Figure 2)

Following the first ToC workshop and the interviews with stakeholders, the Logic Model was reshaped and enhanced. Further details were added to the *inputs*, *activities*, *outcomes* and *enablers* sections of the Logic Model. In particular, the activities section was developed substantially. A consensus was reached that residents should be taught QI theory in a graded approach, including the EQUIP national training sessions at the Annual Urology Bootcamp, but also available as e-learning (numerous of such modules of good quality and with comparable introductory QI content are already freely available) and hospital-based training (thus maximizing the use of existing resources where the residents are physically located). This should be further consolidated via applying QI techniques within the residents' own hospitals. On the related activity of residents' own QI projects, stakeholders agreed that such projects should have a long-term vision and be conceived in a modular structure, so that individual residents could undertake different elements of the same project. There was strong consensus across stakeholders that QI projects should be delivered through a multidisciplinary team-based approach to include not only residents, but also attendings, nurses, and department managers. Such an approach was thought to allow residents to move

away from the misconception that a QI project is 'theirs alone' to design and deliver, it would provide an opportunity for them to enhance their teamworking ability and to foster a collaborative improvement culture within urology departments. Related to this, at this stage, the Logic Model clearly articulated that project topics should be selected not only to serve the residents' interests but also the organizational and departmental improvement needs (e.g., projects should be undertaken to address issues identified in hospital quality reports for urologic services). Key enablers for national implementation that this phase of the research specified included support from the Specialty Advisory Committee (SAC) for urology (which is part of the national Joint Committee on Surgical Training in the UK) and from the British Association of Urological Surgeons (BAUS). Both bodies have the decision-making power to support formal embedding of QI elements into the national curriculum; and the clout to signal, culturally, that QI projects are valued and should be prioritized by residents. The elements of the Logic Model that were not developed in adequate detail in this phase included the need for a web-platform to host urologic QI projects completed by residents, and also the need to quality-appraise residents' completed QI projects. Capacity development at national level was also not specified.

Phases 3-4 (Figure 3); final Logic Model

In the final phases of the study, stakeholders' input through the second ToC workshop and the final set of interviews resulted in mapping of the implementation activities in a greater level of depth and in detailed articulation of the anticipated barriers/enablers. In this phase of the research, no major new themes were added to the Logic Model, instead, existing ones were refined and specified. There was strong consensus that for EQUIP to be nationally sustainable in the long-term, the General Medical Council (GMC) represents an additional

major national stakeholder. The GMC had been reviewing surgical curricula and there was a timely opportunity to feed the EQUIP evidence-base into the review process. In this phase, there was further reinforcement of the need for the modular nature of QI projects, so to involve more than one resident and to be carried out across multiple hospitals. More senior residents could undertake leadership and management roles in such projects; and more junior residents could find an entry point into QI, through being assigned specific QI techniques to deliver within such projects (e.g., a larger QI projects requiring two rounds of Plan-Do-Study-Act (PDSA) methodology could engage a leading senior resident to offer project leadership and oversight; and two junior residents, to undertake and report one PDSA cycle each). Attendings and other senior team members (nurses and managers) should assist and mentor the residents. Project selection could be further informed from national improvement priorities for urologic surgery (e.g., focused on addressing national clinical audit findings), so as to be addressing real clinical need and allow the residents' work to achieve real clinical impact. Residents' own interests was noted to also be relevant in project selection.

The Logic Model also specified the reporting format for such projects, with consensus being that an established framework could be used, such as a version of the 'Standards for QUality Improvement Reporting Excellence' (SQUIRE) guidelines.³¹ This would also facilitate peer-reviewed publications (valued as a CV-building element by the residents), as these guidelines are well-accepted by improvement science and surgical journals for the reporting of QI studies. Homogeneity in project reporting was deemed a useful feature for a national web-platform. The platform should offer a searchable repository of residents' completed QI projects, which future residents could use as methodological exemplars, and replicate in their own work, hence facilitating shared learning. The platform should also list currently ongoing QI projects nationally, so that residents could identify projects of interest and join them. However, the question of where such a platform may be optimally hosted did not reach a

Journal Pre-proof

consensus recommendation. Potential options that the stakeholders suggested should be explored included hosting the web-platform (i) within the BAUS website (www.baus.org.uk); (ii) within a multi-specialty platform focused on clinical improvement, such as the National Health Service Improvement website (www.improvement.nhs.uk) or the 'Getting it Right First Time' program website (www.gettingitrightfirsttime.co.uk). A urology-specific host would have the benefit of being familiar to both urology residents and attendings. In contrast, a multi-specialty website host would facilitate future application to other surgical specialties.

The final Logic Model detailed the approach to expand capacity for QI training and supervision. A pyramid approach to capacity building was agreed upon: (i) basic training, for both residents and attendings, to develop an understanding that allows satisfactory participation in QI projects; (ii) intermediate training for more engaged attendings wishing to supervise QI projects; and (iii) advanced training for urology attendings wishing to become part of UK-wide 'QI Faculty for Urology'. Hospitals (providing protected time away from clinical duties) and national bodies (providing certification) were recognized as key enablers to achieving such tiered training provision. Further, training could be consolidated through formal appointment of 'QI champions' at local (hospital) and regional (training rotation) levels, who could offer further supervision and mentoring to residents.

Figure 3

DISCUSSION

The study achieved both aims we set out to address. Regarding our first aim, we arrived at a finalized Logic Model, which specifies the elements that need to be in place and the logical sequence of activities to be undertaken by major program stakeholders to achieve successful scale-up of EQUIP. The Logic Model also specified both educational and also clinical

impacts of EQUIP once it has been nationally scaled: the former include increased capacity for QI work and an established QI network across the country; the latter include improvement in the processes of urologic care delivery and improved outcomes and experience of care by patients. The ToC thus achieved the technical objective of an agreed implementation plan for EQUIP. Regarding our second aim, we found the application of the ToC methodology within this study feasible and useful. In addition to meeting the technical objective of specifying the core elements of an implementation plan for EQUIP, the ToC allowed us to engage hands-on a wide range of senior stakeholders across several UK (and some European) organizations. Through the study, participants developed first-hand understanding of EQUIP, and were able to directly feed into the future planning through their contributions to the workshops and individual interviews. The ToC method thus achieved good stakeholder engagement.

The study offers methodological innovation in the field of surgical education. ToC methodology has been widely applied to complex clinical and public health programs. To the best of our knowledge, this is the first time the ToC approach is applied in the context of a surgical education program aimed at national scale-up. Doing so is both coherent with existing educational theory and also advances it. Well-established curriculum development frameworks typically propose a staged approach. For instance, the Kern curriculum development framework (which was used in the initial development of the EQUIP QI training module¹⁶) includes the following steps:³² (1) Problem identification and general needs assessment; (2) Targeted needs assessment; (3) Setting goals and objectives; (4) Specifying educational strategies; (5) Implementation of the curriculum; and (6) Evaluation and feedback. In light of the current study, we propose that the ToC approach can be used in conjunction with the Kern framework as it allows surgical educators to specify in some detail steps no. 5 and 6 – i.e., the curriculum implementation and metrics of relevance to the curriculum evaluation that go beyond individual learner assessments. The ToC methodology

allows bridging of the 'knowledge-action' gap – i.e. the actual outcome of the method is an implementation plan that engages with the key people and organizations that facilitate its application. To-date, the way surgical curricular innovations are implemented often relies on senior leadership alone. This study demonstrates how the ToC qualitative methodology can offer scientific rigor to planning how educational innovations can be designed for large-scale application and support senior surgical leadership in implementing such innovations.

Practically, a ToC should be undertaken for each new curriculum development, or every time an existing curriculum is applied in a new area: ToCs are by definition context-specific, hence prior successful implementation does not guarantee similar successful implementation elsewhere. Moreover, a ToC should be undertaken prior to curriculum scale-up, or widespread implementation. By its very nature, the ToC allows program directors and educators to identify potential pitfalls and barriers to curriculum uptake and successful application. Such application of ToC methodology can address a common weakness in many otherwise excellent educational curricula: their implementation is often poor or partial. Even the best designed educational program will not meet its intended educational targets if not well applied. Studies have documented such implementation challenges even in strongly nationally-led curricula. For example, the ACS/APDS Surgical Skills Curriculum faced significant resource, logistical and educational challenges in its implementation, which were identified through descriptive studies post-implementation.³³ We propose that such educational initiatives would benefit from ToC studies carried out at the pre-implementation phase, which could identify and to address potential implementation barriers pre-emptively. The study has limitations. As a qualitative method, the validity of a ToC relies on the inputs of the participants who develop it. Although we took care to include relevant stakeholders to the ToC development, key stakeholders might have been omitted. A different group of

participants might have produced a different ToC. The EQUIP senior leads (JSAG, NS) took

care to avoid introducing bias to the workshop proceedings or interviews by not participating, however they had/have working relationships with some of the study participants (e.g., joint membership of national committees); hence social desirability bias in participants' contributions cannot be fully ruled out. Thematic extraction was done via consensus-driven coding. This approach to coding was useful in bringing together clinical and scientific perspectives on the themes, but meant no inter-coder reliability estimates were produced. A ToC typically offers a valid representation of the stakeholders' thinking at the time of development; however significant external events may impact on its components over time. In our case, the viability of the overall implementation plan has been impacted by the COVID19 pandemic response, which has caused delay. Finally, use of a ToC supports but does not guarantee successful implementation. The study did not produce objective data on actual implementation of the EQUIP at national scale in the UK, or data from residents' QI projects that have improved patient care, these are limitations inherent to the method, which is only a first step of an implementation process. Prospective objective data need to be collected to demonstrate implementation success and clinical improvements.

Future research in the context of EQUIP requires prospective application of the ToC and formal evaluation of what nationally scaled QI training achieves. The study is timely in the UK, where the Academy of Medical Royal Colleges recently published an expert-driven curriculum for use by all surgical and medical residencies, which specifies the elements of QI residencies should teach (but not how to achieve that). This development suggests that the future will bring more emphasis on QI skills for UK residents. We take the view that future research should aim to support both residents (in building up their skills to deliver strong QI projects) and also training program directors (in offering them a plan to deliver the recommended curriculum successfully). To achieve this, the EQUIP program should aim to:

(i) design a web-platform for urology residents' QI projects; (ii) develop a train-the-trainers

module for urology attendings to allow them to teach and supervise QI projects; and (iii) maintain ongoing liaison with BAUS as a national leader and champion of QI across urology departments and residencies. Prospective evaluations are needed, to objectively assess the implementation process (including its uptake and barriers) and also the actual clinical impact of residents' QI projects, which is the ultimate objective of teaching them QI skills. Further studies that apply ToC methodology to surgical curricula in other countries and settings will corroborate the utility of the method in surgical education.

Conclusions

Theory-of-Change methodology was useful in developing a stakeholder-driven, actionable implementation plan for national scale-up in the UK of a newly developed QI skills program for urology residents. Prospective application of the plan and further evaluations will follow.

REFERENCES

- Vincent C, Moorthy K, Sarker SK, et al. Systems Approaches to Surgical Quality and Safety. *Ann Surg*. 2004;239(4):475–82.
 https://doi.org/10.1097/01.sla.0000118753.22830.41
- Sevdalis N, Hull L, Birnbach DJ. Improving patient safety in the operating theatre and perioperative care: obstacles, interventions, and priorities for accelerating progress. Br J Anaesth. 2012;109 Suppl 1:i3-i16. https://doi.org/10.1093/bja/aes391
- Ounounou E, Aydin A, Brunckhorst O, et al. Nontechnical Skills in Surgery: A
 Systematic Review of Current Training Modalities. *J Surg Educ*. 2019;76(1):14-24.

 https://doi.org/10.1016/j.jsurg.2018.05.017
- Storesund A, Haugen AS, Flaatten H, et al. Clinical Efficacy of Combined Surgical Patient Safety System and the World Health Organization's Checklists in Surgery: A Nonrandomized Clinical Trial. *JAMA Surg*. Published online May 13, 2020. https://doi.org/10.1001/jamasurg.2020.0989
- Treadwell JR, Lucas S, Tsou AY. Surgical checklists: a systematic review of impacts and implementation. *BMJ Qual Saf.* 2014;23(4):299-318. https://doi.org/10.1136/bmjqs-2012-001797
- Vaidya A, Aydin A, Ridgley J, et al. Current Status of Technical Skills Assessment
 Tools in Surgery: A Systematic Review. *J Surg Res.* 2020;246:342-378.

 https://doi.org/10.1016/j.jss.2019.09.006
- 8. Ahmed K, Miskovic D, Darzi A, et al. Observational tools for assessment of procedural skills: a systematic review. *Am J Surg*. 2011;202(4):469-480.e6. https://doi.org/10.1016/j.amjsurg.2010.10.020

- 9. Ounounou E, Aydin A, Brunckhorst O, Khan MS, Dasgupta P, Ahmed K. Nontechnical Skills in Surgery: A Systematic Review of Current Training Modalities. *J Surg Educ*. 2019;76(1):14-24. https://doi.org/10.1016/j.jsurg.2018.05.017
- 10. Hull L, Sevdalis N. Advances in Teaching and Assessing Nontechnical Skills. *Surg Clin North Am.* 2015;95(4):869-884. https://doi.org/10.1016/j.suc.2015.04.003
- 11. Henrickson Parker S, Flin R, McKinley A, Yule S. The Surgeons' Leadership Inventory (SLI): a taxonomy and rating system for surgeons' intraoperative leadership skills. *Am J Surg.* 2013;205(6):745-751. https://doi.org/10.1016/j.amjsurg.2012.02.020
- 12. The Heath Foundation. Quality improvement made simple (2nd ed.).

 https://www.health.org.uk/publications/quality-improvement-made-simple; 2013

 Accessed 12 June 2020
- 13. Healthcare quality improvement partnership. Guide to quality improvement methods.
 https://www.hqip.org.uk/resource/guide-to-quality-improvement-methods/; 2015
 Accessed June 12, 2020
- 14. Mason SE, Nicolay CR, Darzi A. The use of Lean and Six Sigma methodologies in surgery: a systematic review. *Surgeon*. 2015;13(2):91-100. https://doi.org/10.1016/j.surge.2014.08.002
- 15. Pallari E, Hughes-Hallett A, Vitoratou S, et al. Assessing the current state of quality improvement training in urology in the UK: Findings from the General Medical Council 2018 trainee survey. *J Clin Urol*. Published online June 2, 2020:2051415820920523. https://doi.org/10.1177/2051415820920523
- 16. Pallari E, Khadjesari Z, Green JSA, Sevdalis N. Development and implementation of a national quality improvement skills curriculum for urology residents in the United Kingdom: A prospective multi-method, multi-center study. *Am J Surg*. 2019;217(2):233-243. https://doi.org/10.1016/j.amjsurg.2018.11.008

- 17. Pallari E, Khadjesari Z, Green JSA, Sevdalis N. The effectiveness, implementation and evaluation of quality improvement training programmes in surgery: a BEME systematic review protocol.
 - https://bemecollaboration.org/Reviews+In+Progress/Quality+improvement+training+programmes+in+surgery/; Accessed June 12, 2020.
- 18. Pallari E, Khadjesari Z, Biyani CS, et al. Pilot implementation and evaluation of a national quality improvement taught curriculum for urology residents: Lessons from the United Kingdom. *Am J Surg*. 2020;219(2):269-277.
 https://doi.org/10.1016/j.amjsurg.2019.11.011
- 19. Morris ZS, Wooding S, Grant J. The answer is 17 years, what is the question: understanding time lags in translational research. *J R Soc Med*. 2011;104(12):510-520. https://doi.org/10.1258/jrsm.2011.110180
- 20. Hull L, Athanasiou T, Russ S. Implementation Science: A Neglected Opportunity to Accelerate Improvements in the Safety and Quality of Surgical Care. *Ann Surg*. 2017;265(6):1104-1112. https://doi.org/10.1097/SLA.00000000000002013
- 21. Breuer E, Lee L, De Silva M, Lund C. Using theory of change to design and evaluate public health interventions: a systematic review. *Implement Sci.* 2016;11. https://doi.org/10.1186/s13012-016-0422-6
- 22. Funnell SC, Rogers PJ. Purposeful Program Theory: Effective Use of Theories of Change and Logic Models. San Francisco: John Wiley & Sons; 2011.
- 23. De Silva MJ, Breuer E, Lee L, et al. Theory of Change: a theory-driven approach to enhance the Medical Research Council's framework for complex interventions. *Trials*. 2014;15:267. https://doi.org/10.1186/1745-6215-15-267

- 24. Davidoff F, Dixon-Woods M, Leviton L, Michie S. Demystifying theory and its use in improvement. *BMJ Qual Saf.* 2015;24(3):228-238. https://doi.org/10.1136/bmjqs-2014-003627
- 25. W.K. Kellogg Foundation. Logic Model Development Guide.
 https://www.wkkf.org:443/resource-directory/resource/2006/02/wk-kellogg-foundation-logic-model-development-guide; 2004 Accessed June 12, 2020
- 26. Saunders B, Sim J, Kingstone T, et al. Saturation in qualitative research: exploring its conceptualization and operationalization. *Qual Quant*. 2018;52(4):1893-1907. https://doi.org/10.1007/s11135-017-0574-8
- 27. Guest G, Bunce A, Johnson L. How Many Interviews Are Enough? An Experiment with Data Saturation and Variability. *Field Methods* 2006;18(1):59–82. https://doi.org/10.1177/1525822X05279903
- 28. Pavelin K, Pundir S, Cham JA. Ten Simple Rules for Running Interactive Workshops. *PLoS Comput Biol.* 2014;10(2):e1003485. https://doi.org/10.1371/journal.pcbi.1003485
- 29. Ritchie J, Spencer L. Qualitative data analysis for applied policy research. In: Bryman A, Burgess RG, eds. *Analysing qualitative data*. London: Routledge; 1994:173-194.
- 30. Pope C, Ziebland S, Mays N. Analysing qualitative data. *BMJ*. 2000;320(7227):114-116. https://doi.org/10.1136/bmj.320.7227.114
- 31. Ogrinc G, Davies L, Goodman D, Batalden P, Davidoff F, Stevens D. SQUIRE 2.0 (Standards for QUality Improvement Reporting Excellence): revised publication guidelines from a detailed consensus process. *BMJ Qual Saf.* 2016;25(12):986-992. https://doi.org/10.1136/bmjqs-2015-004411
- 32. Thomas PA, Kern DE, Hughes MT, Chen BY. *Curriculum Development for Medical Education: A Six-step Approach.* 3rd ed. Baltimore: Johns Hopkins University Press; 2016.

- 33. Korndorffer JR, Arora S, Sevdalis N, et al. The American College of Surgeons/Association of Program Directors in Surgery National Skills Curriculum: adoption rate, challenges and strategies for effective implementation into surgical residency programs. *Surgery*. 2013;154(1):13-20. https://doi.org/10.1016/j.surg.2013.04.061
- 34. Academy of Medical Royal Colleges. Training for better Outcomes: Developing quality improvement into practice. https://www.aomrc.org.uk/reports-guidance/developing-quality-improvement-into-practice/; 2019 Accessed November 20, 2020.

Table 1: Stakeholder participants' roles and organizational representation

Stakeholders & organizations represented in the study*	1 st ToC Workshop (n=10)	1 st round of stakeholder interviews (n=6)	2 nd ToC Workshop (n=10)	2 nd round of stakeholder interviews (n=4)
National training policy-makers				
Chair of Specialist Advisory Committee in urology ¹	✓	✓		
National specialty associations / specialist societies				
BAUS former president				✓
BAUS educational lead for residents	✓			
BAUS educational lead for attendings		✓		
BAUN president ¹		✓		
Chair of BSoT committee ¹	✓			
EAUN president	✓		✓	
National QI program leads				
GIRFT clinical lead for urology				✓
Practising clinicians				
Attending urologist (n=11)	✓	✓	✓	✓
Senior urology nurse specialist (n=3)	V	✓	✓	
Renal physician	✓		✓	
Primary care physician ¹		✓		
Residents				
Urology residents (n=3) ¹	✓		✓	
Service managers				
Head of quality and efficiency improvement			✓	
Managing director ¹	✓			
QI and patient safety director				✓
Patient and Public Involvement				
Patients (n=3) ¹	✓		✓	✓
Third sector representatives				
CEO of the Urology Foundation ¹	✓		✓	
Academic experts				
Professor of urology		✓		
Associate professor of urology	✓			
Professor of medical education ¹		✓		
Program lead for improvement science	✓			
Royal College of Physicians QI faculty member	✓		✓	
Specialty-specific academic journals				
JCU Chief Editor ¹		✓		
BJUI Chief Editor		✓		

^{*} Stakeholders representing more than one role/organization are documented for each role/organization under the relevant type of representation.

¹ Stakeholders indicated with subscript of 1 were members of the study Steering Group.

Abbreviations, in alphabetical order: BAUN = British Association of Urological Nurses; BAUS =
British Association of Urological Surgeons; BJUI = British Journal of Urology International; BSoT
= BAUS Section of Trainees; CEO = Chief Executive Officer; EAUN = European Association of
Urology Nurses; GIRFT = Getting It Right First Time; JCU = Journal of Clinical Urology; QI =
Quality Improvement.

FIGURE CAPTIONS

Figure 1: EQUIP Initial Logic Model (developed by the research team, based on evidence)

Abbreviations: GMC = General Medical Council.

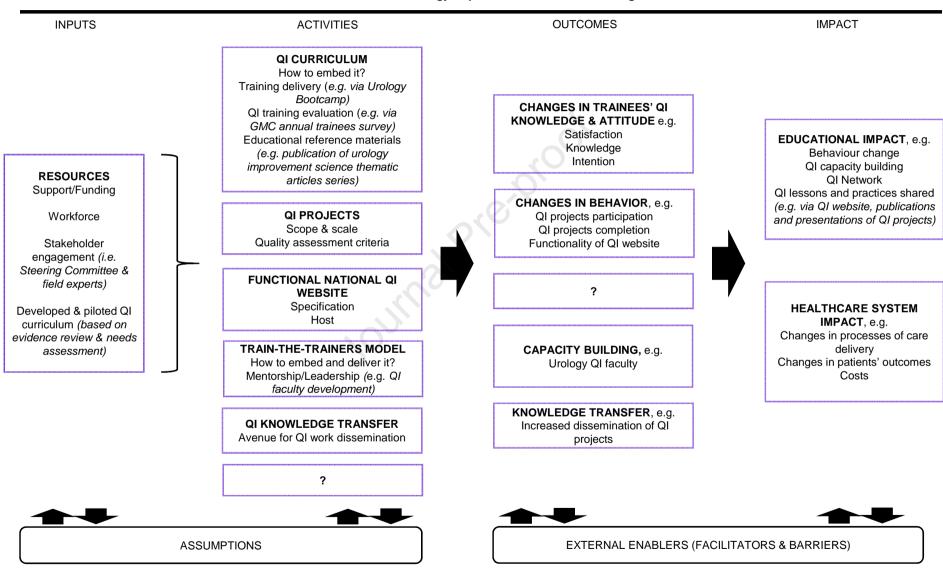
Figure 2: EQUIP revised Logic Model (following 1st stakeholder workshop, June 2019)

Abbreviations: BAUS = British Association of Urological Surgeons; CQC = Care Quality Commission; NHSE = National Service Health England; NHSI = National Health Service Improvement.

Figure 3: EQUIP final Logic Model (following study completion, October 2019)

Abbreviations: BJUI = British Journal of Urology International; CQC = Care Quality Commission; GIRFT = Getting It Right First Time; IJUN = International Journal Urological Nursing; ISCP = Intercollegiate Surgical Curriculum Program; JCU = Journal of Clinical Urology; JME = Journal of Medical Education; JSE = Journal of Surgical Education; NHSE = National Service Health England; NHSI = National Health Service Improvement; SAC = Specialist Advisory Committee.

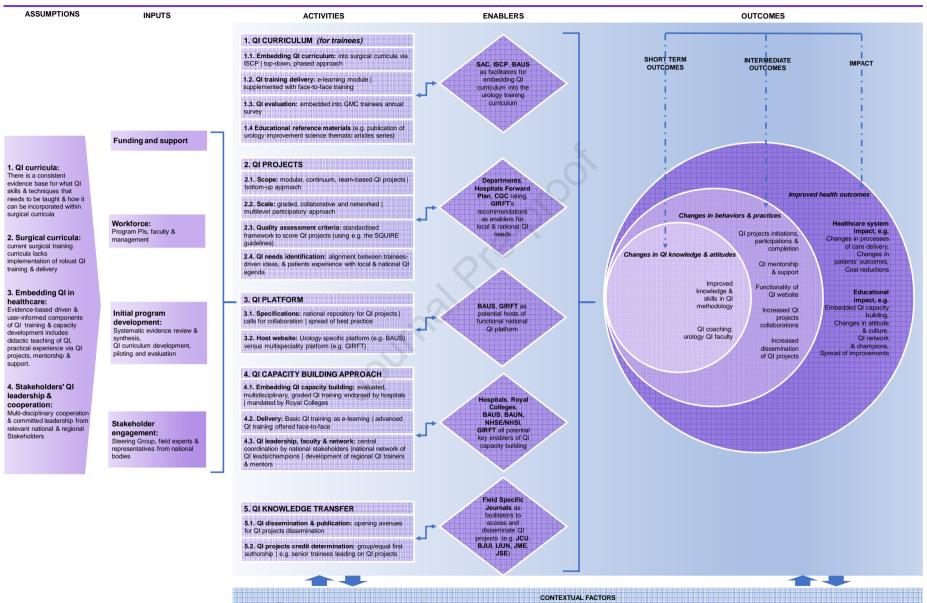
PURPOSE: To develop a nationally scalable, evidence-based and user-informed training and capacity development program in quality improvement skills to embed in all urology departments in the United Kingdom



How to achieve the aim

PURPOSE		United Kingdom				
m		Support/Funding				
INPUTS		Workforce				
Ĭ		Stakeholder engagement (i.e. St	, ,			
		Developed & piloted QI curriculum (based on evidence review & needs assessment)				
Finding a leverage point	Consolidate available educational/QI resources & support (e.g. e-learning modules) that can be leveraged to embed QI training in urology					
	Finc	Appraise enabling online platforms that already exist, before developing a QI website				
_	_	Embed QI curriculum into the urology training curriculum				
ACTIVITIES Capacity fer building	ity gc	QI projects scope & scale: defined as needs-based & long-term with hierarchal-modular participation; establish a standardised criteria to appraise QI projects				
	apac	Functional QI website specifications & host: to identify enabling national platform for QI projects				
	ОФ	Multidisciplinary approach to QI capacity building, including train-the-trainers model & streamlined leadership				
	QI needs identification: to align organizational & trainees' needs (e.g. turning hospital quality reports to actionable QI projects; undertaking local quality gap assessment based on patient experience, at departmental level, clinical experience, etc.)					
	ds & trans	Avenue for QI work dissemination & overcoming barriers (e.g. access to speciality peer-reviewed journals)				
QI needs & knowledge transfer	QI nee wledge	Development of QI educational reference materials (e.g. publication of urology improvement science thematic articles series via Journal of Clinical Urology)				
	kno	•				
SS		Specialist Advisory Committee in urology (part of the Joint Committee on Surgical Training) facilitator for embedding QI curriculum				
H R		BAUS facilitator for QI training delivery & support with developing functional national QI website				
ENABLERS		CQC, NHSE & NHSI potential enablers for the alignment of national QI needs to local needs & obtaining hospital buy-in				
		Journal of Clinical Urology/British Journal of Urology International to facilitate access & affordability to disseminate QI projects				
		-				
OUTCOMES		Improved knowledge and skills in QI methodology: Attitude Satisfaction Knowledge Intention	Behaviour change: QI projects initiations, participations & completior QI mentorship & support Functionality of QI projects website			
ಠ		QI coaching: Urology QI faculty	Increased dissemination of QI projects			
		\				
5		Educational impact, e.g.:				
IMPACT	Embedded QI capacity building Changes in attitude and culture QI network & champions QI lessons and practices shared (e.g. via QI platform, publications	Healthcare system impact, e.g.: Changes in processes of care delivery Changes in patients' outcomes Costs				

PURPOSE: To develop and implement a nationally scalable, evidence-based and user-informed training and capacity development programme in quality improvement skills to embed in all urology departments in the United Kingdom



The following contextual factors may act as facilitators or barriers to implementing and embedding QI in medical training, departments & hospitals to ensure scalable and sustainable improvements:

Existing clinical audit infrastructure | local and national level financial backing | buy-in from hospitals' senior management and committed leadership | departments' mandatory engagement in QI work | political will' by national regulatory bodies, i.e. General Medical Council

HIGHLIGHTS

- The 'Theory-of-Change' method helps plan implementation of complex interventions
- Theory-of-Change can be used to plan and facilitate the scale-up of surgical education curricula and an improvement skills curriculum
- Theory-of-Change successfully engaged stakeholders for curriculum implementation

CONFLICT OF INTEREST STATEMENT

NS is the director of London Safety & Training Solutions ltd, which provides training and advisory services to healthcare organizations and training programs globally. The other authors report no conflicts of interest.