

Reverse Innovation in healthcare

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Complete List of Authors:	Skopec, Mark; Imperial College London Issa, Hamdi; Imperial College London Department of Surgery and Cancer Harris, Matthew; Imperial College London
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Standfirst – A Review of opportunities and challenges to learn from low- and middle-income countries

Mark Skopec¹, Hamdi Issa², Matthew Harris¹

- ¹ Department of Primary Care and Public Health, Imperial College London
- ² Institute of Global Health Innovation, Imperial College London

Introduction

The notion of developed countries as the main producers of healthcare innovation is being increasingly challenged (1). Between 1985 and 2009, the annual growth rate of patent applications in developing countries was 19% and they more than doubled their share of global patent applications between 1985 and 2009 (2). This, together with the need for frugality in high-income country (HIC) health systems, means that increasingly low or middle-income countries (LMICs) are a source of innovations that HICs could learn from. Innovations that have been ideated, trialled, tested and initially adopted in LMICs, before spilling over into HICs, have become known as Reverse Innovations (RI) (2–4). In this Analysis, we review RI, the opportunities and challenges they present in healthcare, and provide examples of several potential RIs that would have significant benefit for the NHS.

Reverse Innovations – examples and opportunities

In 2009, when General Electric (GE) announced its \$3bn investment to create low-cost healthcare innovations (3) one of those innovations was the GE Mac 400, a handheld, portable electrocardiogram (ECG) device that costs \$1,000, a fraction of the cost GE normally charges for its regular ECG devices. The Mac 400 was initially developed for use in rural India, but was so successful, that GE then began selling it in the U.S. as well, where doctors in many isolated communities faced the same challenges as those in rural India (3). The frugality of the handheld device, coupled with its clinical efficacy, has made many wonder why they should pay the premium price for traditional ECG machines, when they can obtain one that is just as effective for a fraction of the cost (3).

This is an example of a RI, an innovation that was first developed in a LMIC before being adopted in a HIC. RI is not limited to technologies or products. Kangaroo care is a

practice that involves skin-to-skin contact between a preterm infant and their parent for 24h a day, as well as exclusive and frequent breastfeeding (5). This method was first introduced in Colombia nearly 25 years ago, used in lieu of expensive neonatal intensive care unit (NICU) (5). Its positive impact on infant mortality, infection and length of hospital stay as well as its impact on mother-infant bonding, breastfeeding and maternal satisfaction is well documented and has led to its routine use in maternity units throughout the developed world (5). The Ponseti Technique for treating Congenital Talpes Equino Varus (CTEV), commonly known as clubfoot, was scaled in LMICs such as Malawi (6) and Uganda (7), which are home to 91% of 174,000 children born with clubfoot each year (8,9) as an alternative to expensive surgical correction. Since then, multiple studies have been published on the efficacy of the treatment in these settings (6,10), and the technique is now the de facto gold-standard method of treating clubfoot in the U.K. as well (11). Finally, the Tree of Life approach to counselling originated in Zimbabwe and is used to support groups to overcome collective trauma they may have faced through a narrative technique based on Zimbabwean folklore (12). It can be used with both children and adults and has been adopted by several Mental Health Trusts across the U.K. demonstrating to have positive outcomes (12,13).

RIs, by virtue of their origin, development or scaling in LMICs, tend to be frugal innovations, doing more, with less for more people, driven by the necessity to use resources more efficiently (14,15). The resulting technologies, techniques or models tend to deliver care at a comparable level to best practice in high-income settings but at a fraction of the cost. The potential of RIs is being increasingly recognised. The Norwegian Government's international development department, Norec (formerly known as fk Norway), mandates that the international partnerships that they fund be mutually beneficial, through exchange of personnel and expertise with LMIC partners, to support the possibility of RI back into Norway. In the U.K., institutions such as the Tropical Health Education Trust (THET) through their Health Partnership schemes and Health Education England through their Earn, Learn and Return schemes and the Global Health Exchange, are increasingly looking to identify innovations from LMICs that would benefit the NHS, by supporting overseas professionals to work in the NHS or to identify innovations overseas and promote them back in the U.K. THET's *In Our Mutual Interest*, and the Chief Medical Officer's Annual Report (2019) both call for NHS organizations to genuinely learn from LMICs (16,17).

In Table 1 we list several innovations that have been ideated, developed, trialled or scaled in low-income settings and which deserve further examination and consideration for

piloting in the U.K. NHS. Each innovation has different selling points, evidence bases and rationales for adoption in the U.K. For example, a modelling study examining the benefit to the U.K. of adopting the Brazilian Family Health Strategy (FHS) model of community health worker-based primary care suggests that if used in the U.K. at scale it could provide 753,592 additional cervical cancer screenings, 365,166 additional breast cancer screenings, and 482,924 additional bowel cancer screenings, as well as provide MMR1 vaccinations for an additional 16,398 children at 12 months and 24,716 MMR2 vaccinations at five years of age (18), all by identifying those individuals eligible for these services but that have not yet been reached. The Arbutus Medical Drill Cover System (AMDCS), a technology commercialised from a technique originating in Malawi, converts an ordinary hardware drill into a surgicalgrade drill by inserting it into a reusable, sterile bag. Cost savings associated with the AMDCS could range between 85% and 94% compared to the existing technology used in the NHS and could save individual Trusts £250k each per annum (19). Mosquito net mesh used for hernia repair has been found to be vastly cheaper than commercial mesh (US\$ 0.0043 compared to US\$ 108; respectively) (20,21) and meta-analyses of head-to-head RCTs conducted in several LMICs (India, Uganda and Burkina Faso) have shown comparable effectiveness in terms of adverse events, relapse and infection rates (22). With 100,000 NHS bed days spent on open mesh hernia repair each year, the use of the mosquito net mesh would present a significant cost saving. Autotransfusion with the Hemafuse device is currently used in Ghana and Kenya. It takes approximately 10 minutes to use, and costs roughly US\$ 60 per patient, compared to US\$ 250 for a bag of donor blood (23) and could offer a viable solution to many of the shortages of donor blood faced in the NHS. Each of these examples present unique opportunities and challenges for piloting and then scaling but the potential for cost saving without jeopardising patient care is significant.

Challenges to Reverse Innovation – principles and practice

Innovations from LMICs are not, however, inherently beneficial to high-income health systems. For example, the potential market for Prepex, a non-surgical circumcision device used at scale in sub-Saharan Africa is likely to be quite small in the U.K. where circumcision is mostly for religious reasons and conducted shortly after birth, rather than as a strategy to prevent HIV transmission in adult life. Frequently, the innovations are neither patented nor owned by a particular enterprise and this presents challenges in terms of obtaining both regulatory approval and entry to new markets, as is the case with the mosquito net mesh. Furthermore, one of the features of frugal innovations is that they are often

repurposed technologies, and this is a challenge for example when it comes to obtaining CE marking, as is the case of the Arbutus drill. There are documented attempts to adopt innovations from low-income settings but that have not provided the intended benefits. Conditional cash transfer (CCT) programs, for example, have been used to provide incentives for students to attend school and perform well on exams (24,25), as well as to encourage patients to adhere to their medication regimes or to their weight loss programs (26,27). The Oportunidades program in Mexico has been among the most successful CCT programs (28) and led the New York City Mayor's Office to implement a similar CCT program for lowincome families living in New York City, called Opportunity NYC – Family Rewards (29). The overall effects of the Family Rewards program were mixed. Though there was a decrease in poverty and material hardship during the course of the pilot (29), educational effects were most pronounced among academically prepared 9th graders, but not seen among their lessproficient peers (29). It resulted in a small increase in the rates of health coverage, but there was no observed increase in preventive doctor visits (29). The failure to demonstrate impact in one setting does not on its own undermine the potential or rationale for RI, but does suggest that tailoring to contexts, careful evaluation and a preparedness to adapt the intervention will be important.

All these are specific challenges related to the specific innovations, their features and the contexts where they are adopted. However, there are general challenges that are also worth considering. There is an obvious tension in the use of the term 'Reverse Innovation' in that it undermines the very paradigm shift in knowledge translation that it seeks to promote. The notion that innovation flows from HIC to LMICs in 'normal' circumstances and that adopting innovations from LMICs into HICs is a reversal of that process can be construed as perpetuating a hegemonic view of knowledge production as a whole (30). Related to this is when to document an innovation as a RI? Zedtwitz et al present a typology of RI that considers the geography of the ideation, development and scaling of the innovation (2). They propose therefore that there are several types of RIs ranging from those that are stronger types that have been ideated, developed and scaled in LMICs before spilling over to HICs (2). And there are weaker types, those that may have been ideated first in HICs, before being tested, and scaled in LMICs, where the barriers to entry and regulatory barriers might be less, and then re-entering HIC markets once proof-of-concept has been established (2). The Ponseti technique is a good example of this. Although it was scaled in LMICs, it was in fact first developed by the orthopaedic surgeon Dr Ingnacio Ponseti Vives at the University of

Iowa in the 1950s (9). Narrating the trajectory and spread of RIs is challenging, not least because there are very few documented examples of this type of knowledge flow (9). It is rare for attempts to adopt innovations from LMICs, whether successful or failed, to be published or even documented. Equally, it is challenging to identify high-value, low-cost frugal innovations from LMICs in the first place. These types of innovations, oftentimes work-arounds or quick fixes to intractable local health service delivery issues, are not patented, not evaluated and not documented. Some notable databases are available such as the Centre for Health Market Innovations, the WHO Compendium for Technologies for Global Health, but many remain under-the-radar. The U.K. NHS's extensive commitment to overseas volunteering and partnership is an opportunity to identify innovative practice for the NHS and if well documented could become a repository for innovative solutions.

Finally, whilst much progress is being made to level the playing field in global health innovation, there remains extreme inequity in terms of the production, publication and consumption of healthcare research and innovation, favouring the Global North (31–33). It is well documented in the marketing and consumer research literatures that the country-of-origin (COO) of a product serves as a cue for quality, reliability and safety (34,35) and it is well-known that products from LICs are discounted early on because of this extrinsic cue. COO effects are therefore likely to play a particularly vital role in the adoption and diffusion of innovations which have been ideated, developed, and primarily marketed in LMICs (2,36,37). There is a need to challenge the biases that continue to favour the dominant, often North American and Eurocentric narrative around global innovation diffusion. By considering the value of adopting LMIC innovations in HICs, as well as through recognising the contributions to science of countries from which they originate, we can create an innovation landscape that is more equitable. The related decolonization movement, which challenges us to see entrenched power structures, is a useful impetus to make us aware of the unconscious biases that undermine social and cognitive justice (38,39).

Conclusion

Despite the growing literature surrounding RI, only a select few have been successfully implemented in the healthcare field. There are many specific and general challenges to the adoption and diffusion of RI in the U.K. However, considering the need for frugality and cost-savings in the NHS, and the wide variety of low-cost, high-value innovation originating in LMICs, there is a health service need for a concerted effort to

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contexts.

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Innovation	Country of	Unique selling point	Evidence base	Rationale for adoption	Probable challenges
. Duna-ilia n	origin	FUC to an a supervising a physician a groups	Current and annuaries of FUC	A LL K was a delline actually favored that if	Took objection the NUIS to a SUNA based
Brazilian	Brazil,	FHS teams comprising a physician, a nurse,	Cross-sectional comparison of FHS	A U.K. modelling study found that if	Task-shifting the NHS to a CHW-based
Family	inspiring	a nurse assistant and 4-6 full-time	enrolees to non-enrolees and those on	CHWs were to successfully engage	system would require a fundamental
Health O Strategy	similar	community health workers (CHWs) serve	private health plans found that FHS	with just 20% of all eligible but	restructuring of the system. As there are
Juli dice 87	models in	populations of up to 1,000 households with	enrolees were more likely to have	unscreened and unimmunised	other fundamental differences between
1 (FHS)	South Africa	no overlap or gap between catchment	usual source of care, to have visited a	individuals, they could provide	the Brazilian and U.K. health systems (such
4	and Angola	areas. FHS is rapidly scalable growing from	doctors or dentist within the past year,	753,592 additional cervical cancer	as differences in baseline health provision,
3		2,000 teams with 60,000 CHWs serving 7	to have access to their required	screenings, 365,166 additional breast	health needs and health inequalities),
4		million people in 1998 to 39,000 teams	medications and to find the care they	cancer screenings, and 482,924	there is no guarantee that employing
5		with more than 265,000 CHWs serving 120	received satisfactory, compared to	additional bowel cancer screenings, as	CHWs in the NHS would have the same
6		million people in 2014 (40).	non-enrolees and those on private	well as provide MMR1 vaccinations	measurable effects as in Brazil. Further,
7			plans (41). Two longitudinal analyses	for an additional 16,398 children at 12	situating the newly-trained CHWs in the
8			found that due to FHP coverage	months and 24,716 MMR2	highly specialized primary care workforce
9			unnecessary hospitalisation for	vaccinations at five years of age, all at	of the NHS could prove difficult.
0			ambulatory-care sensitive chronic	a cost of £2,22bn annually (18).	
			diseases (stroke, CVD, and asthma)	Employing CHWs in the U.K. in a	
1			declined at a statistically significant	systematic fashion could potentially	
2			rate (42), and that FHP coverage was	reduce unnecessary workload on GPs	
:3			negatively associated with mortality	by identifying problems early and	
4			rates from cerebrovascular and heart	supporting chronic disease monitoring	
.5			diseases (43).	(18).	
Arbutus	Canada,	The AMDCS converts a regular hardware	User feedback from surgeons who have	Musculoskeletal disease accounts for	The drill system is FDA approved but lacks
Medical	commerciali	drill into a surgical-grade drill by creating a	used the device has been positive. The	greater than 25% of surgical	CE marking. Distributors prefer to sell
B Drill Cover	sed from	sterile barrier around the device (44).	AMDCS has been used in 30,000	interventions in the NHS and has the	fewer 'big-ticket' items to improve their
System	techniques	Following surgery, this pouch can be	patients in 50 hospitals across 15 LMICs	third largest budget at £10bn (45).	margins, rather than repeatedly selling
(AMDCS)	developed	autoclaved and subsequently reused,	with no difference in clinical outcomes	Nearly all orthopaedic interventions	low-cost items such as the AMDCS.
	in Malawi,	precluding the need for purchasing often	identified to date (19) although formal	require the use of either a surgical	competition with other low-cost
1	in use by	expensive, sterilisable surgical drills (44).	evaluation is pending.	drill or saw. A modelling study found	manufacturers in LMICs, as well as with
2	Canadian			that cost savings associated with the	large, well-established firms in the medical
3	military in			AMDCS in the NHS could range	device industry in HICs will be high.
4	several			between 85% and 94% and could lead	Clinicians must use the device as
5	LMICs			to significant cost savings for Trusts if	instructed, as there have been reports of
6				used at scale (19).	bags being used beyond their life span
,					(19).
8 Mosquito	Burkina	In many low-resource settings, surgeons	Prospective trials with a limited	Roughly 70,000 surgeries were	Asking surgeons to change their practice
net mesh	Faso,	have resorted to using mosquito nets as a	number of participants established that	performed to repair inguinal hernias	and use an unfamiliar material may prove
for hernia	Cameroon,	raw material from which to cut	using sterilised mesh was both safe and	in England in 2001/02, comprising	challenging. Additional effort involved in

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3 repair	Ghana,	appropriately-sized pieces of mesh to use	effective (47,48). Randomized	0.14% of the population and	cutting large nets down to size and
4	India, Ivory	in hernia surgery (46). After pieces have	controlled trials (RCTs) were	accounting for 100,000 NHS bed-days	sterilising them before surgery, present
5	Coast,	been cut to size, they are sterilised and	undertaken establishing no significant	of hospital resources (50). Open mesh	another barrier. There is no long-term data
6	Uganda	subsequently implanted (46).	difference in short-term clinical	repair is the preferred surgical	to support the efficacy of mosquito net
7			outcomes (20,49).	technique to remedy inguinal hernias,	mesh for hernia repair, as most trials only
8		· ·	Mosquito net mesh has been found to	performed by 96% of U.K. surgeons	monitored up to 12 months post-surgery.
9			be vastly cheaper than commercial	(51).	There is a theoretical risk of mesh material
		()/	mesh (US\$ 0.0043 compared to US\$	No cost-effectiveness analyses have	distortion at U.K. standard autoclave
10			108; respectively) (20,21).	been performed in a high-income	temperatures (52) leading to concerns of
11				context, but there is potential for	prion disease transmission if sterilised at
12				significant cost savings to the NHS.	lower temperatures. This requires
13				g a rate of	substantiation in order to ensure that
14		7/			double standards in clinical practice
15					between HIC and LMIC contexts are
16			' / } :		avoided.
17 Friendship	Zimbabwe	The Friendship Bench (FB) is a community-	An RCT from 2016 investigating the	Around 1 million people received	Shifting the NHS' mental health facilities
18 Bench		based intervention focused on delivering	effectiveness of the intervention found	some form of psychological therapy	from a primary-care-focus to a community-
19		brief psychological interventions for	that in the group of individuals who	for a common mental disorder in the	based model will require a significant
		common mental health disorders, such as	received the intervention, had lower	U.K. in 2016/17, and 1 in 6 people	investment in terms of time and effort.
20		anxiety and depression with the assistance	symptom scores of anxiety and	experience a bout of depression or	Training lay health workers in both mental
21		of lay health workers (53). Patients are	depression after 6 months as	anxiety each week (57). Additionally,	health and cultural competencies, so that
22		referred to the benches by clinicians,	compared to those who received the	people living in deprived areas are	they may have productive conversations
23		where they receive up to six 45-minute	usual standard of care (54). Cost-	less likely than average to recover	with potential patients may entail a
24		counselling sessions and may be referred	effectiveness analyses of a similar	from their condition after	significant up-front investment.
25		to other health or social services (53).	programs in Chile and India found that	psychological therapy (57). Eight CCGs	ов
26		,	a stepped-care approach to mental	are expected to miss their required	
22 23 24 25 26 27			health, and the use of lay health	mental health investment standard	
28			workers was more effective and only	for the second year in a row (57).	
29			marginally more expensive than	Task-shifting mental health care to a	
30			treatment in primary care (55) and had	multicomponent stepped-care	
31			a sustained effect on depression	program, could provide much-needed	
22			outcomes over a 12-month period	relief to the NHS' mental health	/h .
32 33			while maintaining cost-effectiveness	facilities.	/) /.
			(56).		
34 Sayeba's 35 method 36 37 38 39	Bangladesh	An improvised intrauterine tamponade	A prospective study of 23 women	PPH is the second leading cause of	Sayeba's method is unlikely to replace
35 method		consisting of a condom secured to a sterile	conducted in Bangladesh, found that in	direct maternal deaths in the U.K.	other frontline treatment for PPH in a
36		rubber catheter using a piece of string (58).	all 23 patients, bleeding stopped within	(62). A 2019 report by MBRRACE-UK	hospital setting in HICs, where different
37		The catheter is inserted into the uterus and	one hour of the intervention, patients	identified the need to 'Improve care	catheters may be more readily available
38		subsequently inflated using saline solution	did not go into irreversible shock and	for women with haemorrhage' (63).	than condoms. Further, medicinal
39		to control postpartum haemorrhage (PPH)	there was no infection detected (59). A	There is also an increased emphasis	management is likely to remain the
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		resistant to medicinal treatment (58)	systematic review of different uterine	on the availability of births at home or	preferred method of treatment in the
			balloon tamponade methods found	in midwife-led contexts (62). Using	hospital setting. Changing these guidelines
			that Sayeba's method was the most	Sayeba's method to control PPH could	would require robust evidence, as well as
			commonly used device in resource-	address both points. Other	the endorsement from professional
			poor settings (60). Sayeba's method was successful in 186 of 193 cases (60).	advantages, include the availability of the materials used, rapid insertion	associations such as the Royal College of Obstetricians and Gynaecologists, as well
			Prices to create uterine balloon	requiring no anaesthesia, and ease of	as MBRRACE-UK.
		()	tamponades vary from US\$ 225	the procedure, which can be	as Wibrnack-Or.
			oesophageal catheters to US\$ 0.19 for	performed by relatively inexperienced	
			condom catheters (61), suggesting a	personnel (61).	
			high potential for cost-effectiveness.		
Zipline –	U.S.A.,	Zipline was established in 2014 to improve	70% of the population in Rwanda live	Underserved communities without	Regulatory hurdles are likely to be the
Drone-	marketed	access to medical supplies for people living	in rural areas, indicating that	regular access to medical care are not	biggest barrier to implementing Zipline in
based	and scaled	in remote locations (64). The first	healthcare is likely not easily accessible	unique to LMICs. Zipline has	HICs. As was seen in the U.S., there are
delivery for	in Rwanda	healthcare delivery service was started in	for most of the rural population (68).	recognised this and has started to	several guidelines laid out by the Federal
medical supplies		Rwanda in 2016 (65). Drones – called 'Zips'	Zipline partnered with the Rwandan	implement plans to bring medical	Aviation Agency (FAA) that could severely
supplies		- can carry up to 1.8kgs of medical supplies	government to enable delivery of over	supplies to communities in several	restrict the ability of Zipline to function
		(66). Blood transfusions make up the majority of Zipline's deliveries (67).	50 different medical products to serve those communities living in remote	U.S. states, such as Maryland, Nevada, and Washington, as well as to Native	effectively. For instance, in the U.S., Zipline is not allowed to deliver goods at night,
		Medical practitioners request a delivery via	areas of the country. For instance,	American communities. As the	and their drones are not allowed to fly
		a text message or the Zipline App and are	since Zipline's establishment in	telemedicine market continues to	over people (72). A thorough
		notified one minute prior to delivery to	Rwanda, many mothers who give birth	grow in the U.K. (71), Zipline could	understanding of the regulatory landscape
		'walk outside and receive [their] delivery.'	in remote areas no longer need to be	provide a complementary service to	facing drones in the U.K. is necessary
		Boxes with supplies are dropped from the	transported to centrally-located	the increasing telemedicine offerings.	before Zipline's services can be offered.
		Zip using a paper parachute (66). By relying	hospitals in the event of PPH, as blood		·
		on drones, Zipline not only ensures fast	transfusions can be delivered directly		
		delivery of medical supplies, but they are	to them on-demand (69). Zipline's	10.	
		also able to lower costs compared to land-	success is beginning to spill over into		
		based delivery by up to 50% (66,68).	other LMICs. A second distribution		
			centre was opened in Ghana in 2019,		
			with plans to open more over the		/_
			course of the next four years (70).		
			Zipline also seeks to expand to Indonesia in the future (66).		1//1
Peek Vision	United	Peek Vision's innovative approach to eye	Nonclinical photographers using the	The number of people living with sight	Though Peek Vision's smartphone-based
	Kingdom,	health system strengthening is centred	smartphone-based adapter for optic	loss in the U.K. is set to increase	technologies could be easily used in the
	marketed	around a smartphone-based vision	disc imaging were as effective at	steadily, reaching 4 million by 2050	U.K., their holistic approach to
	and scaled	screening app, as well as real-time data	acquiring optic nerve images as	(77). The indirect costs due to partial	strengthening the eye health system would
	in	reporting and eye health service analytics	ophthalmic assistants using desktop	sight and blindness were estimated at	likely not find traction in the NHS. Peek
	Botswana,	(73)	retinal cameras (74). A cluster RCT	more than £4mn in 2008 (77). At least	specifies that, 'We work with our partners

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11 12	Zimbabwe and Pakistan U.S.A., marketed and scaled in Nigeria, Kenya and Ghana	Sproxil's suite of products (called Sproxil Solutions) empower consumers to play an active role in detecting and combatting counterfeit drugs. Sproxil Defender is a point-of-sale product code, also known as Mobile Product Authentication (MPA) which allows consumers to authenticate the medication they have purchased (80)	found that the Peek school eye health system showed increased adherence to hospital referral for visual impairment among school children compared with the standard approach (75). Peek Vision has expanded to Botswana, Zimbabwe and Pakistan (76). Sproxil's MPA codes have been used over 8.5 million times by consumers to verify a range of different products, from pharmaceuticals to automotive parts and electric cables. Law enforcement is able to use cell-phone tracking data to identify hot-spots for counterfeit medication (80). Sproxil launched in Nigeria, but has since expanded to Kenya, Ghana and India (80).	half of all sight loss is avoidable (77). The simple and effective screening provided by Peek Vision, which has also shown increased adherence to follow-up visits (75) could significantly impact the burden of disease in the U.K. The global incidence of counterfeiting has increased by 51% between 2011 and 2015 (81). 11 cases of falsified or counterfeit medicines were detected in the U.K. between 2001 and 2011 (81). In 2013, £12m worth of counterfeit medicines were seized in the U.K. as part of a week-long international operation (82). In the event of a no-deal Brexit, the U.K. will be left out of an E.Uwide system to combat counterfeit drugs (83). A 2016 study testing the efficacy of medication authentication technology in the U.K. found that the technical detection rate was at 100%, though because of low compliance with scanning at the start of the study, only 31% of counterfeit medicines were detected (81). A user-friendly, easily scalable system such as Sproxil could prove beneficial in the U.K.	to assess unmet needs for eye health services,' (78). This unmet need would likely not be identified in the U.K., where the NHS provides 13 million eye tests per year (79). The U.K. has collaborated heavily with the E.U. on the E.U.'s Falsified Medicines Directive (FMD), which offers protections against counterfeit drugs should the U.K. remain in the E.U. in some capacity (83), making a system such as Sproxil obsolete. In the absence of such regulatory frameworks, compliance may be the biggest hurdle, as evidence by Naughton's 2016 investigation (81). Ensuring buy-in and participation, which will require contributions from manufacturers, pharmacists and consumers could prove challenging.
33	Israel, marketed and scaled thoughout sub-Saharan Africa	Prepex is an elastic ring-controlled radial compression device that is designed to offer non-surgical male circumcision (84). Its primary use has been to rapidly scale up voluntary medical male circumcision (VMMC) in Sub-Saharan Africa in order to prevent the transmission of new HIV infections (84).	Multiple trials have confirmed the safety and effectiveness of the Prepex device for VMMC (84–86). The procedure can be performed by relatively inexperienced personnel, in non-sterile settings in approximately 4.5 minutes, without anaesthesia or sutures (87). The device is in use in 13 countries in Sub-Saharan Africa with high HIV prevalence (87). Costeffectiveness analyses have been	New HIV cases in the U.K. continue to decline (90). The Prepex device is unlikely to be used for the prevention of new HIV infection as it is in Sub-Saharan Africa. Prepex could offer a significantly cheaper, quicker and less painful alternative to men who require circumcisions for medical or other reasons. Current procedures are carried out on a day-patient basis, require general anaesthesia, sutures	The number of circumcised men is declining in the U.K. (92). In communities where circumcisions are performed for religious reasons, it is unlikely that the Prepex device would be used, as it may not be in accordance with cultural traditions. In light of the low frequency with which the procedure is performed, expending effort to convince practitioners to switch from surgical to non-surgical circumcision may not be seen as a high priority.

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			conducted in several African countries	as well as the prescription of pain-	
+			(86,88,89), concluding that Prepex can	killing medication (91). These	
5			be cost-effective if human resources	expenses could be avoided by using	
j			are employed effectively.	Prepex.	
Hemafuse 3 0 1 2 3 4 5 6 7 8 9	U.S.A., marketed and scaled in Kenya and Ghana	The Hemafuse is a manually operated autotransfusion device that can be used to collect a patient's blood during an internal haemorrhage. It is subsequently retransfused back to the patient, thereby addressing the lack of donor blood available in many emergency and resource-constrained settings (93).	The process of autotransfusion has been proven to be clinically safe and effective (93). Autotransfusion devices used in many parts of the Global North, however, are expensive and rely on a power source, whereas the Hemafuse device can be operated manually by a single individual (23). The autotransfusion process using the device takes approximately 10 minutes, and costs roughly US\$ 60 per patient, compared to US\$ 250 for a bag of donor blood (23). The device is currently being sold in Kenya and Ghana (94), and the company will soon be expanding to India (95).	Over the past five years, the number of men giving blood in the U.K. has fallen by roughly 25% (96). The NHS has identified a shortage of donors in three areas with majority black African and black Caribbean populations (97). Further, it is estimated that although about 8% of people have O negative blood, O negative constitutes 13% of requests from hospitals (98). Autotransfusion could offer a viable solution to many of the shortages of donor blood faced in the NHS. Especially for hospitals unable to afford expensive autotransfusion devices, the Hemafuse could be a cost-effective	In areas where enough donor blood is available, it is unlikely that autotransfusion will become the new standard of care. Additionally, Hemafuse cited 'friendly regulatory environments' as a reason for seeking approval in Kenya and Ghana (94), implying that the process of obtaining regulatory approval for their device may be significantly more difficult in places like the U.K.
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