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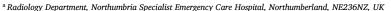
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Portable X-rays-A new era?

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ABSTRACT

This paper reports learning points from a small pilot study using a portable diagnostic X-ray set to radiograph patients in novel settings such as the patient home or care home. This paper explores issues associated with regulatory compliance, staff training, oversight of radiation safety and the drafting of key risk safety documentation including risk assessments. Some limitations to diagnostic imaging are explored and a simple subjective assessment of the visual clarity presented. The pilot demonstrated potential for starting treatment sooner without recourse to a hospital visit. It was well received by patients and all images were of diagnostic quality but was more labour intensive compared with traditional methods. Likely barriers and potential advantages to implementing a full clinical service are discussed.

Introduction

Planar X-ray procedures often form an integral part of any patient journey. In many cases, the process of radiology is likely to be one of the key factors in determining initial progress along the patient pathway. Currently it is the norm for a patient in need of an X-ray to attend an acute hospital, diagnostic hub, or similar centre, prior to any treatment commencing. Previously, it had been the norm to X-ray certain infirm patients within their own home [1], but this practice largely ceased following the introduction of new ionising radiation regulations from 1999 onwards [2,3].

In 2014, the National Health Service (NHS) published a review [4], which concluded there was a need to provide more care locally and to encourage integrated out-of-hospital care facilities. There was an appreciation that provision of facilities within a community setting, such as a health centre, diagnostic centre, shopping centres or leisure facility could improve patient access and reduce waiting times. A further review [5] looked at services providing healthcare in community settings instead of hospitals and concluded that older patients may benefit. In a separate report [6], it was concluded that care home residents receiving enhanced support within the care-home setting were admitted to hospital as an emergency 23% less often than others who had not received that support. In 2019, the NHS forward plan [7] promoted the implementation of diagnostic hubs. Later that year the NHS England and NHS improvement produced a report entitled "Planning to reduce avoidable conveyance" [8] and in Oct 2020 an independent review of diagnostic services [9] (including radiology) highlighted an urgent need to further

improve delivery models particularly in the light of pressures resulting from the COVID-19 epidemic.

Recent technological advances, particularly improvements in battery technology and digital X-ray imaging and display have provided an opportunity to explore new ways of providing planar X-ray imaging. One example is the Fujifilm portable X-ray unit FDR x-air [10] (Figs. 1 and 2), introduced into the UK market in Jan 2020.

The X-ray unit itself is compact, $30 \times 26 \times 14$ cm and lightweight 3.5 kg, consisting of a fixed anode X-ray tube broadly similar to a conventional dental set. It delivers 50–90 kV in 2 kV steps and 0.2–2.5mAs in 12 steps. It has an integral lithium polymer 11.1 V 1450mAh battery. According to the manufacturer, it can acquire up to 100 images when new and fully charged. The unit has an integral light beam with adjustable collimators along with selection and display of technique factors. The unit has a fixing point on its underside to enable positioning on a tripod or stand with the exposure initiated from the end of an exposure cable, stored with the main unit, or carried separately. There is separate charger and cable. When used alongside one or more high sensitivity DR detectors linked to a laptop with proprietary low dose, X-ray imaging software, the system is intended to provide diagnostic imaging capability for a range of views including chest, pelvis, and extremity. The manufacturers promote the device as suitable for a range of medical X-ray applications outside of the hospital setting. The manufacturer states [10] that this may include radiography within the patient's home, where local regulations allow.

Given the technology currently available and the increased importance now being placed on diagnostic testing in settings other than an acute hospital, a review of the possible role of radiography within the home, care home or similar setting may be considered timely.

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Fig. 1. Photograph of Fuji X-air on tripod with exposure cable in situ.

This paper reports relevant findings and learning points from a small pilot study using the Fuji X-air within the patient's home environment and in some other locations such as a GP surgery and care home.

It had been agreed in advance by the host NHS trust that although prior approval had been obtained from the Caldicot guardian in relation to the processes involved, formal ethical approval was not required for this project. While the X-ray equipment differed from any used previously within the organisation, the standards of equipment manufacture and vendor support were unchanged and the pathway into clinical service (including medical physics checks and staff training) were as per any other X-ray set. However, given the differences in the environment for delivery, special documentation and operating procedures were required in addition to some data collection for clinical audit purposes. These elements are the subject of this paper. The presented data and analysis are part of a service evaluation and therefore do not require formal ethical approval.

Operational details of the pilot study, including clinical drivers and overall outcomes have been described elsewhere [11]. This paper explores issues associated with regulatory compliance within the broader range of settings addressed by the study, including the patient home.

The paper also details requirements for staff training, risk assessments, local rules, audit, and oversight of radiation safety. In addition, some limitations to diagnostic imaging are indicated including a subjective assessment of the visual clarity for the resulting images. Finally, some suggestions for further roll out and/or development are included.

Method

The X-ray department of an NHS specialist emergency care hospital in the county of Northumberland obtained the Fuji x-air system on loan from the manufacturers for a period of roughly 6 months for the purposes of the pilot study. Prior to use, the unit was tested in accordance with the employer's established procedures for new X-ray equipment. In addition to providing the usual equipment evaluation prior to entering service, testing in this case also aimed to judge whether the system could be used as a viable alternative to conventional mobile radiography. Commissioning tests included assessment of X-ray output and variation with tube loading, kilovoltage, exposure time, focal spot size and alignment of light beam with radiation beam. The radiation safety evaluation included inspection and testing of tube labelling, tube leakage and exposure control. Testing of the associated digital image detector included an evaluation of dose indicator calibration, non-uniformity, noise power spectrum, modulation transfer function and contrast detail.

These data, along with documentation currently in use within the host organisation formed the basis of a suite of written procedures suited to the varying arenas of use. Senior radiographic staff collaborated with the employer's medical physics expert (MPE) and radiation protection adviser (RPA) to establish suitable risk assessments, X-ray local rules and procedures relating to The Ionising Radiation (Medical Exposure) Regulations 2017 (IRMER), and to ensure that suitable arrangements existed to support these working procedures. This involved visiting in advance a range of sites including care homes and GP hubs within the community and liaising with a broad range of professional groups, including care home staff, ambulance staff and emergency care doctors.

IRMER operators with experience in a senior role and, where possible, in receipt of training as a radiation protection supervisor, were identified in advance and received practical equipment related training and ongoing support from the company's application specialist.

To gauge the potential for diagnostic imaging prior to any patient use and to investigate possible limitations in imaging, erect chest radiographs were carried out on an adult anthropomorphic phantom (PBU-50 Kyoto-Kagagu [12]) designed to produce realistic planar radiographic



Fig. 2. Photograph of Fuji x-air showing control panel and display on rear of unit.

Table 1
Tube and generator test results.

	Value	Result
Test date	27-Jul-20	
Alignments (maximum deviation)	13.0 mm	Remedial
Tube potential (maximum percentage deviation)	4.7%	Pass
Timer accuracy (maximum percentage deviation)	0.0%	
Output repeatability (maximum percentage deviation from mean)	0.6%	Pass
Tube Filtration (mm Al)	3.5	Pass
Displayed output calibration factor	0.974	Pass

images. A small series of standard X-ray procedures was simulated over a limited range of X-ray machine settings and phantom body mass index representations. The resulting DICOM chest X-ray images were evaluated subjectively by two radiographers with training and experience in the reporting of chest X-rays. Images were viewed on a laptop to simulate the experience of the operator. Images were ranked for visual clarity against standard indications [13,14], by two radiographers independently, each with training and experience in the reporting of chest X-rays. Evaluators were blinded to the X-ray setting and simulated BMI.

Following acceptance into clinical use but prior to use in a community setting, the equipment was used within the confines of an existing X-ray room to ensure operator familiarity.

Throughout the pilot study, the diagnostic quality of the images and the patient dose indicators were critically monitored in accordance with normal practice. In addition, feedback from patients and carers was encouraged. Practical issues encountered were addressed by senior staff as they occurred. At the end of the study, the impact on patient management was assessed.

Results

Results of tube and generator tests, shown in Table 1, were satisfactory apart from alignment of X-ray and light fields, which was initially remedial, probably due to large penumbra with collimator blades close to light source. Later, alignment was improved, and some changes made to the exposure cable, exposure factors, carry case and stand. Longer exposure times were noted compared to conventional mobile units. Average output was $59.2\mu Gy$ per mAs at 1 m, 80kVp. Focal spot was 0.8 mm square.

Radiation safety tests assessed effectiveness of mains on indication, visibility and/or audibility of exposure indication, presence of focal spot marker, clarity of markings generally, functioning of dead man exposure cut off and length of exposure cable longer. All results were judged satisfactory. Maximum leakage (top of tube) was $0.08\mu Gy$ per exposure at 1 m, 90 kV, 2.5mAs.

Tests indicated that the Fuji x-air system could deliver a level of performance comparable to that of conventional mobile radiography when using the same digital radiography (DR) X-ray imaging chain. This implied no significant impact on staff dose, patient dose or image quality providing all relevant procedures were followed.

Ongoing equipment testing was generally consistent with normal arrangements for mobile radiographic equipment. Most tests were carried out in a shielded X-ray room prior to departure on each day the equipment was used. These were exposure index (limit+/-15% from baseline), uniformity of image (visual) and alignment (limit +/-10 mm). There was also a weekly check on tube leakage, with a fully closed collimator, by noting whether any image resulted on the DR detector. In addition to these conventional tests, the X-ray set, and the transport case included passive shock monitors to show if there may be accidental impact damage. These were checked prior to and immediately after each transport.

As there was no key-switch or PIN code to guard against unintended exposure, the exposure cable was stored and transported separately. Patient data at the remote site were password protected throughout and the cloud-based image sharing facility was fully encrypted. When away from the base site, equipment always remained within the care of the operator and was returned there after each session.

The employer in respect of both IRMER and the Ionising Radiations Regulations 2017 (IRR) was the acute trust. Arrangements in support of IRMER were similar to elsewhere within that organisation. In particular, the MPE, RPA and radiology manager did not differ from the remainder of the trust, radiographic practice was unchanged, and images were reported as normal for plain film radiography. Referral criteria were as normal except that an additional justification was required to support off-site radiography. It was accepted that the complete range of planar imaging procedures could not be accommodated within this pathway. Accordingly, procedures were limited to chest, hip, pelvis, and extremity. The practitioner was a radiologist (non- attending). One change was that the response was co-ordinated jointly by the ambulance service and radiology department. Most arrangements in support of IRR remained unchanged compared to routine practice, but some changes were required. The employer had been registered with the Health and Safety Executive (HSE) for mobile X-ray generator use. A radiation protection supervisor was appointed with good oversight of the trial. Information leaflets were prepared for staff and public nearby.

An individual radiation risk assessment was prepared in advance for all anticipated locations (such as GP surgeries) based on known data, shown in Table 2. For those cases where a risk assessment could not be prepared in advance (such as patient home and some care homes), an alternative safeguard was devised. This was a guided risk assessment process to assist the operator to determine whether a given location

Table 2
Supporting data for all risk assessments.

Routine Exam	Shielded Primary Air KERMA	
Large Erect Chest	0.01μGy	Shielding afforded by solid wall, assessed at 2 m
90kVp 2.5mAs	per exposure	horizontally from the X-ray focus into space beyond
Hip or Pelvis	$0.02\mu Gy$	Shielding usually afforded by ground floor at 1 m OR solid
90kVp 1mAs (but 80kVp 2mAs typical)	per exposure	wall in unoccupied room ~3 m below BUT occasionally Pb/Cu shielding incorporated into bucky.
Leakage and scatter	Potential staff dose	
2 m from source of scatter/leakage	<1μSv per exposure	Not accounting for shielding by lead coat, etc.
Accident	Potential staff and public dose	
All reasonable	<<0.1mSv	e.g. failure to terminate exposure, poor collimation.

Table 3Breakdown of cases.

Month, year	Total number of referrals	Total number of referrals stood down	Total number of referrals attended	Referrals requiring X-ray	Admissions to the local emergency care hospital	Admissions avoided
Nov, 2020	1	0	1	1	1	0
Dec, 2020	9	0	9	9	4	5
Jan, 2021	10	1	9	8	6	3
Feb, 2021	5	0	5	4	3	2
Mar, 2021	10	1	9	9	5	4
April, 2021	9	0	9	9	6	3
May, 2021	8	0	8	8	2	6
June, 2021	4	0	4	4	0	4
Total	56	2	54	52	27	27

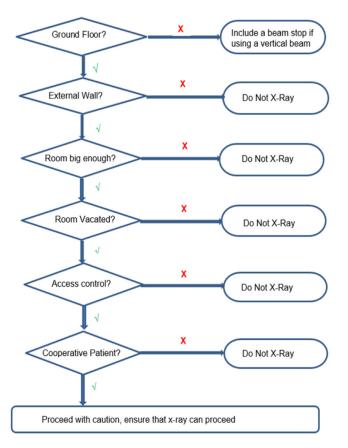


Fig. 3. The guided individual risk assessment process.

would be safe to carry out X-ray work and, if so, what measures would be required. In all cases, the operator, and other members of staff within the vicinity wore a lead apron (0.25mmPb equivalent). For erect chest examinations, any exposure was conditional upon there being a suitable beam-stop (i.e., solid wall or equivalent). For vertical projections, a solid floor could usually be assumed at ground level. However, for patient bedrooms, there was an option of adding a lead/copper beam stop to the bucky. Up to the point of X-ray exposure, the option of not proceeding with the X-ray examination remained. The operator (i.e., senior radiographer) received training to complete a check sheet based on a flow chart, shown in Fig. 3, which was retained on the radiology management system (listed under the relevant patient name) for subsequent review in case of issue. The employer's existing arrangements for incident reporting and for receiving ongoing advice and support from the Radiation Protection Advisor and Medical Physics Expert remained unchanged.

Over the course of the six-month pilot study, 56 patients received an X-ray outside the acute hospital setting. All were in the patient's own

Table 4Observer ranking, visual clarity, phantom chest images, 90kVp, 100cmSID.

		Observer 1	Observer 2
Image A	Simulated BMI 25 0.63mAs Virtual Grid off	3	3
Image B	Simulated BMI 40 2.5mAs Virtual Grid on	4	4
Image C	Simulated BMI 25 0.63mAs Virtual Grid on	2	2
Image D	Simulated BMI 40 0.63mAs Virtual Grid off	6 = worst	5
Image E	Simulated BMI 40 0.63mAs Virtual Grid on	5	6 = worst
Image F	Simulated BMI 25 2.5mAs Virtual Grid on	1= best	1= best

home or care home (no GP surgeries were used). Example clinical images are shown in Fig. 4. The breakdown of cases (Table 3) indicates that exactly half the patients who received an X-ray avoided a subsequent visit to emergency care. No radiation incidents were raised. All images were of diagnostic quality. Feedback from patients and carers was overwhelmingly positive.

Subjective assessments of phantom images were obtained over a range of factors (simulated BMI, mAs, and application of virtual grid). The six images were ranked by trained observers in terms of subjective visual clarity (1=best, 6=worst). Results are shown in Table 4. There was reasonable agreement between the two observers. As expected, images at the lowest mAs and highest BMI were regarded as the worst and were deemed probably worthy of a technical repeat.

Discussion and conclusions

The pilot study ran for over 6 months, mostly at weekends. This was a small pilot study so overall conclusions are limited. One outcome has been to demonstrate proof of concept. It is possible to carry out effective X-ray imaging without the patient attending either a hospital or diagnostic centre. In some cases, this can be done without the patient leaving home.

From a technological perspective, this study has shown that with the use of dedicated image processing, it is generally possible to produce diagnostic images using compact and portable X-ray equipment at exposure settings below those in general use. This has positive implications for both patient and staff dose.

This route has the potential to free up expensive equipment and resources at major centres; it may reduce risks from hospital-acquired infection (including COVID-19) and it is likely to improve the patient experience. In certain cases, it may also enable targeted treatment and management to begin sooner thereby improving outcomes.

There are, however, significant downsides. This route is more expensive and time consuming than conventional imaging and is likely to need a dedicated and highly trained team with effective co-ordination between professionals. However, the above only considers the direct costs. This pathway is likely to be more cost effective when taking the whole service into account, including cost savings resulting from the patient staying at home and reducing needless conveyance via ambulance. It may be relevant that some acute healthcare providers are currently creating patient pathways such as direct referral to the care of the el-

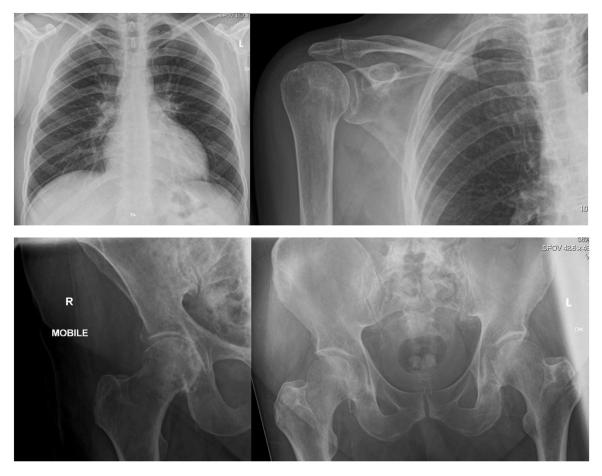


Fig. 4. Examples of actual clinical images.

derly or orthopaedic specialities, bypassing the emergency department. The streamlining of the patient experience in this way may provide a potential tie in with the provision of emergency radiology in the way described in this pilot.

It is clear from this pilot that successful rollout of a service of this nature requires excellent collaborative working arrangements through shared aims. Responsibility for implementation, funding and management would need to be shared between a range of different employers and agencies. However, these challenges are not unique to a service such as this. In fact, much of the initial groundwork in support of collaborative working within the healthcare sector has been documented by the NHS Improvement Agency [15] in relation to diagnostic imaging and the Scottish Futures Trust [16] in relation to the hub programme, a partner-ship programme between the public and private sectors to deliver new community facilities.

The best use of portable X-ray equipment of this type is likely to depend on a number of factors. Servicing rural and isolated areas of population, such as islands, or specific sectors, such as the prison service are two possible examples where there may be particular advantages. However, in general it would also be important to regard the service as complimentary to existing provision.

Further work is required to fully realise the potential of this new radiology pathway.

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